EXHIBIT A

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Dunn et al.

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[54] METHOD OF REGENERATING ARTICULAR CARTILAGE

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[52] **U.S. Cl.** **128/898;** 424/426; 530/840

[58] **Field of Search** 128/898; 424/422, 423, 424/426, 548; 623/16; 530/840

[56] **References Cited**

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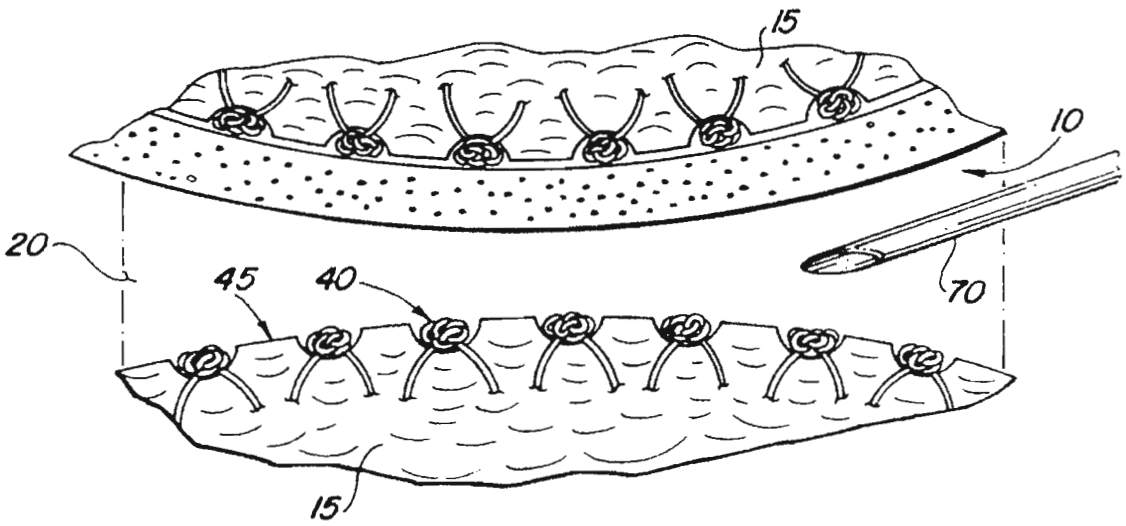
Primary Examiner—George Manuel
Attorney, Agent, or Firm—Malloy & Malloy

[57] **ABSTRACT**

A process for regenerating articular cartilage in a joint including the steps of exposing the joint having a cartilage defect, debriding the entire cartilage layer to the underlying bone-cartilage interface, to expose a plurality of vascular sinusoids in the sub-chondral layer of bone adjoining the joint surface, restoring the smooth contour and topography of the joint to its natural state, surgically closing the joints, and injecting a single dosage of a mixture of purified growth hormone and buffer solution into the joint so as to initiate the regenerative process, said mixture containing a quantity of purified growth hormone (somatotropin) which has been dissolved in a buffer solution.

17 Claims, 2 Drawing Sheets



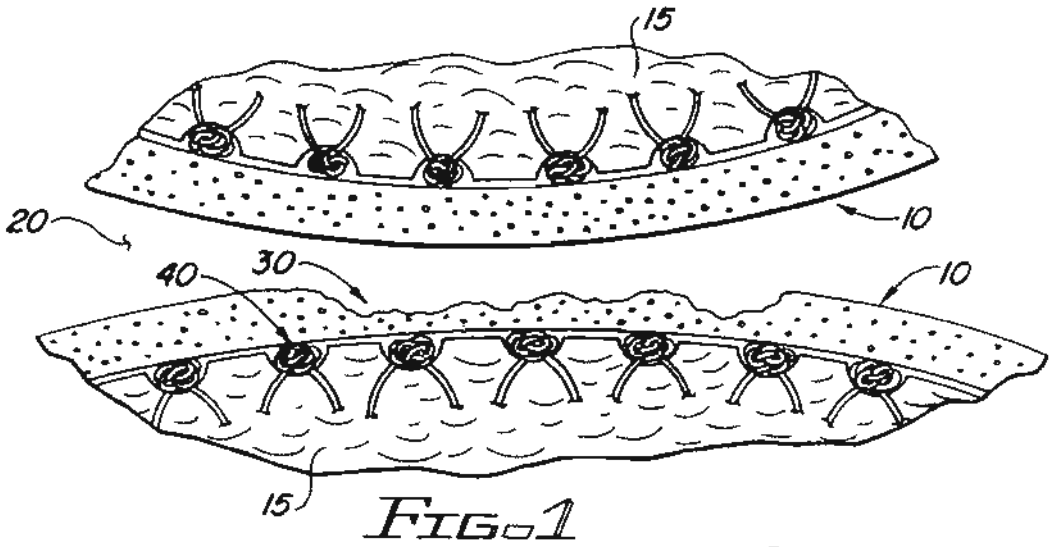


FIG. 1

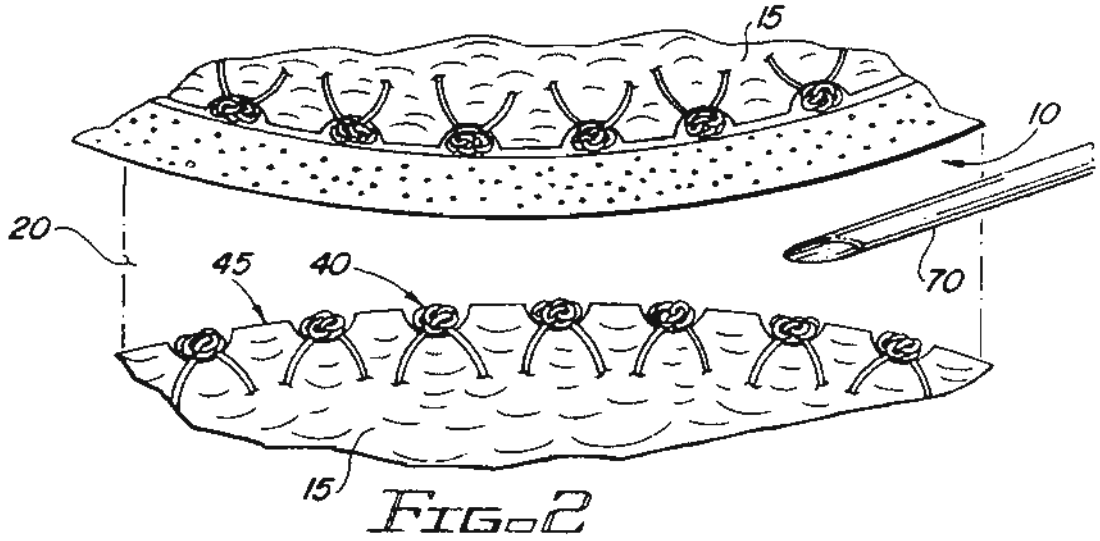


FIG. 2

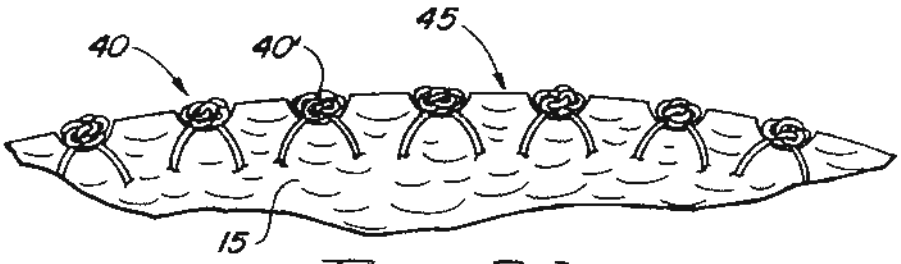


FIG. 3A

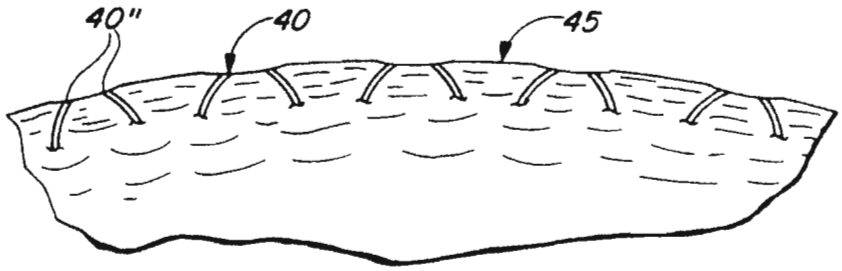


FIG. 3B

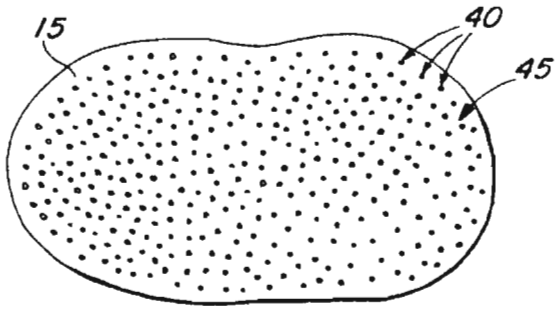


FIG. 4

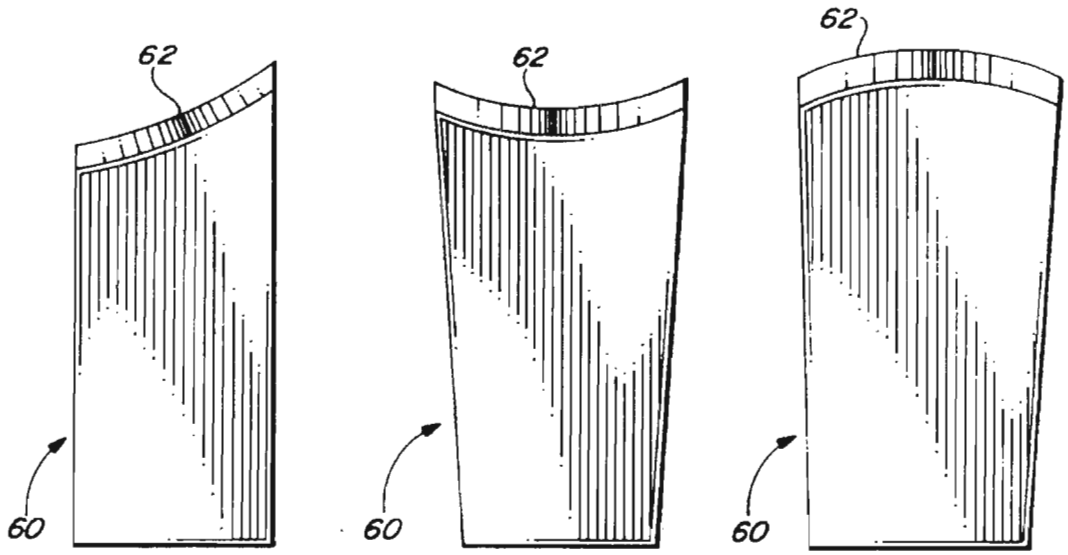


FIG. 5A FIG. 5B FIG. 5C

METHOD OF REGENERATING ARTICULAR CARTILAGE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a process of regenerating articular cartilage surface which has been damaged, destroyed, or has otherwise become defective, thereby alleviating pain, stiffness, and other difficulties associated with a defective articular cartilage surface in a joint.

2. Description of the Related Art

Articular cartilage, the thin, fragile tissue layer covering the ends of bones, allows healthy joints to move freely and without pain. Many arthritic diseases and many degrees of trauma can, however, cause destruction or deterioration of this fragile layer, leading to pain, joint stiffness, and even crippling. From ancient times until the present, it has commonly been believed that this fragile surface, once lost, could never be restored. Attempts made in the past to regenerate or otherwise repair articular cartilage have been failures, thereby directing medical science to the development of substitutes and abandoning the potential for regeneration. Many substitutes have been developed to replace the articular cartilage joint surfaces, and these substitutes require implantations by surgery. Earlier substitutes included fascial transplants or transplants of entire joints such as the knee; however, the majority of these transplants were failures. More recently, medical science has developed implants which utilize metal and plastic components, but these are very costly because of the complicated implant components, the prolonged and repeated hospitalizations required for the surgical implantation of the components and the long periods of rehabilitation. In addition, many cases require one or more revision surgeries to replace defective, loose or infected implants. Most often, full motion and full activity are not achieved with the use of these implants. Further, the general discomfort associated with utilizing such implants makes an alternative method all the more desirable. The biological action of somatotropin acting in this process has been the subject of the applicant's research. The use of growth hormone in this manner is novel; heretofore, growth hormone has always been used clinically to enhance the growth of children with short stature. Somatotropin may have other effects on other organ systems but in the instant patent, the specific actions of somatotropin related cartilage growth which have been identified by Dunn's research are utilized herein. The major targets of somatotropin activity for cartilage regeneration are nests of stem (pleuripotential) cells in the marrow and the vascular system—specifically the vascular sinusoids located at the cartilage bone interface (sub-chondral bone) and the endothelial cells located therein.

The process of regeneration is biphasic. The initial phase, called Morphogenic Phase I, relies on the ability of growth hormone to stimulate proliferation of stem cells in the marrow, and the additional ability of somatotropin to form vascular glomular sinusoids **40'** (Glomeruloids) from pre-existing single lumen vessels **40''** in the sub-chondral bone. The second phase, the Generative Phase, involves the transfer of stem cells from the marrow to the Glomeruloids. Additional stem cells may be provided directly from the endothelial cells located in the vessel walls of the Glomeruloids.

Within these Glomeruloids, the stem cells are transformed into cartilage cells first by transforming into prechondrocytes and then further transforming into chondrocytes. From the Glomeruloid layer, the chondrocytes pass upward and outward to form a new cartilage layer. The matrix of the cartilage layer is simultaneously produced by the new chondrocytes. The dosage of growth hormone to be applied in the single dosage is proportional to the body weight of the patient. The dosages were described above.

Heretofore, growth hormone has been used to augment the height of growth deficient children. The method of this invention relies on a novel use of growth hormone (somatotropin). There is no reliance on transplantation of tissue and thus all of the detrimental conditions of rejection, immune reaction, and failure are avoided. Until the present invention, growth hormone has never been used to regenerate tissue such as articular cartilage.

The method of the present invention is specifically adapted to initiate natural regeneration of articular cartilage on the joint surface through comparatively minor surgical procedures and the injection of one or more dosages of purified growth hormone (somatotropin) to initiate regeneration of and maintain the quality and quantity of articular cartilage. Accordingly, the method of the present invention provides a much needed improvement in the treatment and elimination of ailments associated with the deterioration or destruction of the articular cartilage surface of a joint.

SUMMARY OF THE INVENTION

The present invention is directed towards a method of regenerating articular cartilage in a joint separating two or more bones. Initially, the joint having a cartilage defect is surgically exposed. Once exposed, the cartilage layer of the joint is debrided and the surface is surgically restored to a smooth contour which closely approximates the original surface contour of that joint. For example, the cartilage layer is removed in order that a plurality of vascular sinusoids (Glomeruloids) at the cartilage-bone interface (sub-chondral bone) become exposed. Single lumen vessels are found in adults and glomerular sinusoids (or Glomeruloids) are found in immatures. Thus the term vascular structures or vascular units are generic terms applicable to adults and immatures. After the cartilage layer has been debrided, and the contour of the joint surface restored to a normal configuration, the joint is surgically closed. Next, a quantity of purified growth hormone is dissolved in a buffer solution at a specific range of Ph. The growth hormone dissolved in the buffer solution is then injected as a single loading dose into the joint cavity where it will initiate regeneration of articular cartilage along or at the joint surface.

It is a primary object of the present invention to provide a method which will provide natural regeneration of articular cartilage, thereby eliminating the necessity for transplants or artificial substitutes.

Still another object of the present invention is to provide a method of regenerating articular cartilage which will be effective in providing a new articular cartilage layer in a joint, thereby eliminating or substantially alleviating ailments associated with defective articular cartilage at joints.

A further object of the present invention is to provide a method of regenerating articular cartilage which will

minimize the discomfort associated with loss or damage of the cartilage surface.

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the nature of the present invention, reference should be made to the following detailed description made in connection with the accompanying drawings in which:

FIG. 1 is a cross-sectional view of a joint surface illustrating a deteriorated articular cartilage on the lower joint surface.

FIG. 2 is an isolated view illustrating the application of growth hormone and buffer solution in the joint cavity where it coats all the Glomeruloids or single unit vessels. The lower surface has been debrided of cartilage to expose the sub-chondral bone and whole Glomeruloids.

FIG. 3A is an isolated cross-sectional view illustrating the exposed vascular units at the sub-chondral layer with intact Glomeruloids composed of multiple curved blood vessels.

FIG. 3B is an isolated cross-sectional view illustrating the exposed vascular units at the sub-chondral layer following deep debridement leaving only single lumen blood vessels.

FIG. 4 is a top view of the debrided joint surface illustrating a plurality of fine bleeding points which indicate the presence of exposed vascular units at the sub-chondral layer of bone.

FIGS. 5A, 5B, and 5C are perspective views of the sharpened scrapers to be utilized in the method of the present invention.

Like reference numerals refer to like parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention is directed specifically towards a method of regenerating articular cartilage **10**. Articular cartilage **10**, which is present between bones **15** at a joint **20** so as to provide a bearing type surface for facilitated movement between the bones **15**. If articular cartilage is damaged or deteriorated this can result in significant pain, stiffness, discomfort, and even crippling to individuals suffering from a trauma or other ailments which destroy the joint surface. The articular cartilage **10** is a resilient layer of tissue which covers the ends of bones **15**, and it has been traditionally assumed that once gone, it cannot be regrown or regenerated. The method of the present invention generally includes the steps of surgically exposing a joint **20** having a cartilage defect **30**, removing the cartilage layer **10** of the joint so as to restore a smooth contour which closely approximates an original surface contour of the joint and to expose a plurality of vascular units (Glomeruloids) **40** or single lumen vessels **40''**, see FIG. **3B**, at the cartilage-bone interface, restoring the natural contours of the joint surfaces, surgically closing the joint, and injecting a solution of purified growth hormone dissolved in a buffer solution into the joint so as to regenerate the joint surface.

The method of the present invention is effective as a result of the discovery that in addition to the metaphyseal growth plate which exists near the ends of bones and which makes the bones grow during the maturing process, there is also an articular growth plate at the joint surface **45**. The metaphyseal growth plate, once achieving full growth within the bone, ceases to function in an adult and disappears. The articular growth plate, however, remains intact, although growth-inactive, at the joint surface **10** in the adult. When exposed and properly stimulated by injecting purified growth hormones in the joint as in the method of the present invention, the articular growth plate will resume active growth. In addition under similar stimulation by purified growth hormone, the entire articular cartilage joint surface **10** can be regenerated.

Turning specifically to the method of the present invention, it is directed preferably for use on humans; however, it can be similarly effective with other animals so long as the necessary purified growth hormone is utilized. It is preferred that the growth hormone be species specific which means that human growth hormone would be used on humans and cattle growth hormone would be used on cattle, etc., for instance. When an articular cartilage defect is present in an individual, the joint **20** is first exposed so that the cartilage **10** may be accessed. Next, the cartilage layer **10** at the joint **20** is surgically debrided. This cartilage layer **10** can be removed utilizing various surgical scraping instruments such as curettes and burrs or scrapers **60** designed by Dunn.

These scrapers **60** are designed as templates which mirror the natural contours of the joint surfaces **45**. One edge **62** of the scraper is sharpened (FIG. **5**). It is the sharpened edge **62** that is used to restore the original contour. The primary objective is to restore a smooth contour to the joint surface **45** and to expose a plurality of vascular units Glomeruloids **40** (or single lumen vessel **40''**) at the sub-chondral layer. With regard to the necessity for a smooth contour, further surgical contouring is performed to achieve the desired contour. It is preferred that the contour also closely approximate the original surface contour of that joint so it will function to provide normal movement and to be more comfortable and more natural. It is highly preferred that all of the articular cartilage **10** present be removed so that the regeneration can take effect along the entire joint surface, thereby providing a more uniform regenerated surface. The second important purpose of removing the cartilage layer is to expose a plurality of vascular units (Glomeruloids) **40** or single lumen vessels **40** present at the cartilage bone interface.

As illustrated in FIGS. **3A** and **3B**, the exposed vascular units **40** may preferably include a number of glomerular organelles **40'** composed of multiple curved blood vessels as in FIG. **3A** or single lumen vessels **40''**, as in FIG. **3B**. These individual glomerular organelles **40'**, however may become damaged, either during movement of the joint surface or during removal of the cartilage layer **10**. Accordingly, it can be equally effected to remove sufficiently the cartilage layer **10** and also a portion of the underlying bone **15** so as to expose the number of single lumen blood vessels **40''**, as illustrated in FIG. **3B**. Through use of the growth hormone the single lumen vessels **40''**, will be transformed into Glomeruloids **40** by a morphogenic action (Phase I) of growth hormone which was described previously.

As illustrated in FIG. **4**, once the joint surface is appropriately debrided, a plurality of punctate bleeding points is visible on the joint surface **45**, these bleeding points being a result of the visibility of the sinusoidal layer of bone and the individual vascular units **40** emerging therein, the vascular units **40** often resulting in points of blood at their point of exposure. It is of partic-

7. A method of regenerating articular cartilage as recited in claim **6** wherein said single dosage is about 0.25 to 0.75 milligrams of purified growth hormone per Kilogram of body weight.

8. A method of regenerating articular cartilage as recited in claim **7** wherein repeated, periodic injections of said growth hormone and said buffer solution are made to create and maintain the required amounts of the cartilage.

9. A method of regenerating articular cartilage as recited in claim **1** wherein said vascular units include single lumen blood vessels to be transformed by said growth hormone into glomerular organelles of multiple curved vessels (Glomeruloids).

10. A method of regenerating articular cartilage as recited in claim **1** wherein said vascular units includes glomerular organelles composed of multiple curved vessels.

11. A method of regenerating articular cartilage as recited in claim **10** wherein a lavage with saline during the debridement to prevent cell necrosis which may be caused by friction, heat, or drying of the tissue and cells.

12. A method of producing additional articular cartilage surface thickness, improving the quality and quantity of the existing cartilage, and producing additional crystal clear joint fluid in an individual subject, comprising the steps of dissolving a predetermined quantity of purified growth hormone in a buffer solution, and injecting at least one dosage of said growth hormone and said buffer solution intra-articularly into a joint.

13. A method as recited in claim **12** wherein said dissolving step comprises dissolving said purified growth hormone in a buffer solution comprising Hank's Buffer Solution having a range of pH between 8.0 and 8.3.

14. A method as recited in claim **12** wherein said dissolving step comprises dissolving a growth hormone that is species specific so as to be identical to naturally produced growth hormone.

15. A method as recited in claim **12** wherein said dissolving step comprises dissolving a range of about 1.0 to 1.5 milligrams of said purified growth hormone in 1 milliliter of said buffer solution, the total volume of said dosage being dependent upon the weight of the individual subject being injected.

16. A method as recited in claim **12** wherein said dissolving step comprises dissolving about 0.25 to 0.75 milligrams of said purified growth hormone per kilogram of body weight in 1 milliliter of said buffer solution to form a single dosage.

17. A method of regenerating articular cartilage as recited in claim **14** wherein said injecting step comprises repeated, periodic injections of said growth hormone and said buffer solution into said joint.

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(54) Growth hormone for the treatment of joint inflammation

(57) Treating inflammation in a joint whether heat, redness, pain, swelling and/or stiffness, and for increasing motion and increasing joint space and correcting mal-alignment by injecting one time or multiple repeat times, a single dosage of a mixture of purified growth hormone (somatotropin) and buffer solution into the joint. The present invention also includes injecting or otherwise applying anti-cytokines, anti-kinases, and/or anti growth factors prior to, or simultaneously with, the step of injecting the mixture of purified growth hormone and buffer solution into the joint.

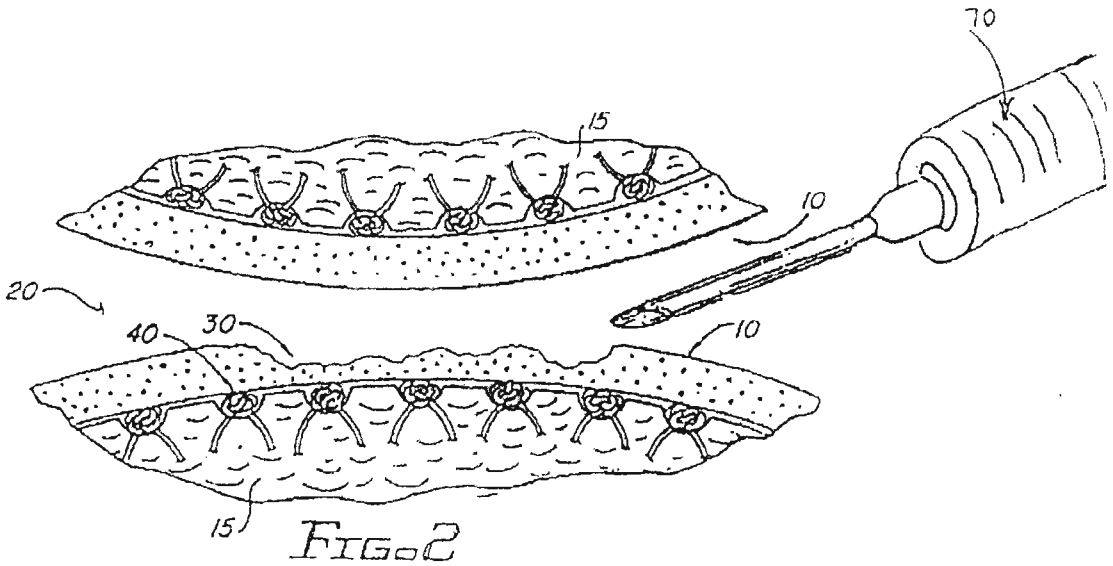

FIG. 2

EP 1 153 607 A2

Description

BACKGROUND OF THE INVENTION

[0001] The present invention relates to a process of treating inflammation in a joint, such as but not limited to a knee joint, a hip joint or an ankle joint, which has been damaged or which has otherwise become defective, and thereby, alleviating pain, heat, redness, swelling, stiffness, and other difficulties typically associated with a damaged or defective articular cartilage surface in a joint. More in particular, the present invention is directed to a process of preparing a joint prior to treatment for inflammation, as described herein, by injecting or otherwise applying a group of agents such as anti-cytokines, anti-kinases, anti growth factors - used individually or in various combinations thereof, to quiet and reduce deleterious activity in the joint prior to the step of injecting a mixture of purified growth hormone (commonly known as somatotropin) and a buffer solution into the joint of a body, preferably but not limited to that of a human, so as to initiate the treatment process.

[0002] The ends of bones which form a joint, including vertebra, are covered by articular cartilage, which is a thin, fragile tissue layer and which allows the bone ends to move freely and without pain. Many arthritic diseases and many degrees of trauma can, however, cause destruction or deterioration of this fragile layer. From ancient times and continuing in the present day, people have suffered through varying degrees of heat, redness, pain, swelling and/or stiffness of the joints, any one or all of which can often be associated with deterioration of the articular cartilage in the joints, whether those joints are associated with walking, such as the hip, knee or ankle joints or others, such as the vertebra of the spine, the shoulder, elbow or wrist joints and fingers. Regardless, damage to and/or the deterioration of articular cartilage in a joint is often, if not always accompanied by inflammation. Inflammation, which is typically thought of as heat, redness, pain, swelling and/or stiffness, when experienced in a joint, can be crippling.

[0003] As a result, many have tried to develop ways to alleviate the pain and inflammation associated with arthritis and other damage to the joints. A number of these efforts have focused on oral medications such as cortisone derivatives (steroids) and numerous non-steroidal anti-inflammatory drugs (NSAIDs), all of which have potentially serious side effects. Other efforts have focused on implants of entire joints, such as the knee or hip, although typically, a lengthy and complicated surgical procedure is required, with the patient being forced to undergo a significant recovery period, including a rigorous and costly regimen of physical therapy thereafter. Most often, full motion and full activity are not achieved with the use of these implants. While medical science has recently developed a variety of new materials for the joint implants, these implants are often more costly, offer results which may be only marginally better than those obtained previously, and do nothing to avoid the hospitalization required for the surgical implantation of them nor the long periods of rehabilitation. In addition, it is also possible that one or more revision surgeries will be needed to replace defective, loose or infected implants. Further, the general discomfort which might be associated with utilizing such implants makes an alternative method all the more desirable.

[0004] The biological action of growth hormone, namely, somatotropin, has been the subject of the inventor's research. Heretofore, growth hormone has been used clinically to enhance the growth of children with short stature. Somatotropin may have other effects on other organ systems but in the instant application for a patent, the specific actions of somatotropin related to its effects on articular cartilage have been focused on by the inventor's research and are utilized herein. The major targets of somatotropin activity are believed by the inventor hereof to be vascular sinusoids and sub-chondral vessels located at the cartilage-bone interface (sub-chondral bone) and the endothelial cells located therein, and in addition, nests of stem (pleuripotential) cells in various sites such as marrow; and the vascular system. More specifically, it is believed by the inventor hereof that growth hormone has the ability to stimulate proliferation of stem cells in the marrow and subchondral vessels and sinusoids. The inventor hereof has also shown that growth hormone has the ability to form vascular and multi-lumen sinusoids, known as Glomeruloids, from pre-existing and mature single lumen vessels in the sub-chondral bone. The inventor describes this action of growth hormone as Morphogenic Action, which is a type of rejuvenation of mature monolumen vessels into fetal-like and/or other immature chondrogenic vascular structures. This Morphogenic Action, a type of rejuvenation, can also dematurate a layer of mature subchondral bone into a cartilaginous state comparable to that observed in the neonatal and immature cartilaginous skeleton.

[0005] The method of this invention relies on a novel use of growth hormone, namely, somatotropin. More in particular, the method of the present invention is useful as an anti-inflammatory agent and is specifically adapted to treat inflammation (heat, redness, pain, swelling, stiffness, etc.) and/or pain associated with damaged and/or defective articular cartilage on or at a joint in a body through the injection directly into the joint of one or more dosages of purified growth hormone (somatotropin). There is no reliance on the transplantation of tissue and thus all of the detrimental conditions of rejection, immune reaction, and other causes of transplant failure are avoided. Similarly, the present invention does not require an individual to undergo a lengthy or complicated surgical procedure, such as those which accompany joint replacements.

[0006] Until the present invention, growth hormone has not, to the inventor's knowledge, ever been used to treat merely the inflammation of tissues such as the soft

tissue components within and surrounding a joint, i.e., synovial lining, capsule, and ligaments and articular cartilage and/or the pain associated therewith. Of course, the inventor herein has heretofore focused on growth hormone as a means for regenerating articular cartilage in a joint, for which U.S. Patent No. 5,368,051 was awarded, incorporated herein by reference, but he has since improved and refined the applications for which growth hormone may be used, as set forth in greater detail, below.

[0007] Accordingly, the method of the present invention provides a much needed improvement in the treatment and elimination of ailments associated with the deterioration or destruction of the articular cartilage surface of a joint, including pain, inflammation of the soft tissue components within and surrounding the joint, including heat, redness, pain, swelling or stiffness. The method of the present invention also is directed towards providing for the reappearance or increase of space between bone ends and restoration of normal alignment of a limb, such as a leg, and including the restoration of normal or nearly normal motion. Further, the present invention is additionally directed towards a preliminary step involving treating a joint with a group of agents such as anti~cytokines, anti-kinases, anti growth factors - used individually or in various combinations thereof, so as to increase the chances that subsequent treatment of the joint for inflammation will be successful.

SUMMARY OF THE INVENTION

[0008] The present invention is directed towards a method of treating inflammation and pain in a joint separating two or more bones. It is pointed out that for purposes of this application, inflammation means pain, joint stiffness, redness, heat and/or swelling, etc.

[0009] The present invention is additionally directed towards a preliminary step involving treatment of the joint with a group of agents such as anti~cytokines, anti-kinases, anti growth factors - used individually or in various combinations thereof - so as to reduce or remove deleterious activity in the joint such that subsequent treatment of the joint for inflammation will likely be successful. More in particular, the preliminary step involves the injection or other application of a group of agents such as anti~cytokines, anti-kinases, anti growth factors - used individually or in various combinations thereof - to a joint about to undergo treatment for inflammation, as described herein.

[0010] Thus, the invention moreover relates to one or more anti~cytokines, anti-kinases and/or anti growth factors, for simultaneous, simultaneous separate or sequential use in the preparation of a joint for anti-inflammation treatment.

[0011] The method comprises an initial step of dissolving a quantity of growth hormone in a buffer solution and then injecting the resulting mixture as a single loading dose into the joint cavity where it will lessen the inflammation of the synovial lining, joint capsule, ligaments and articular cartilage. If desired or needed, additional injections of growth hormone of a single dosage can be injected from one day to several weeks later and after a first set of single or multiple injections, several additional sets of single or multiple injections may be given so as to maintain any improvement of the function of the joint.

[0012] In one alternative embodiment, the method of the present invention may comprise an additional step of mixing an amount of Lidocaine, anywhere from about 0.5 milliliter to 10 milliliters, and ideally about 1 to 3 milliliters of Lidocaine with the mixture of growth hormone and buffer solution. It is contemplated that other injectable anesthetics aside from Lidocaine might also be used with the present invention.

[0013] It is a primary object of the present invention to provide a method for reducing the inflammation of tissue located in or at the joints of a body as well as pain arising at or within the joint of a body without requiring a surgical procedure.

[0014] It is also a primary object of the present invention to provide a new treatment for pain and inflammation in the joint of a body which relies upon a lower dosage of growth hormone and an alternative buffer solution other than that described previously in the applicant's U.S. Patent No. 5,368,051 directed to regenerating articular cartilage.

[0015] A feature thought to arise following treatment of a joint with the present invention is that contact or near contact between the bone-to-bone surfaces is reversed, meaning that a separation, distance or space between the bony surfaces is restored, presumably but perhaps not exclusively because the treatment causes some resumption of growth of articular cartilage, such as that which has been worn down.

[0016] An advantage of the present invention over that disclosed in the Applicant's previous patent is that a range of motion is restored to a joint following treatment.

[0017] Another advantage of the present inventive treatment is the smoothing of irregular joint surfaces and sub-chondral bone and also a reversal of malalignment of the limb following treatment. The present invention thereby eliminates or substantially alleviates ailments in the joints.

[0018] These and other objects, features and advantages of the present invention will become more clear when the drawings as well as the detailed description are taken into consideration.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] For a fuller understanding of the nature of the present invention, reference should be made to the following detai-led description taken in connection with the accompanying drawings in which:

Figure 1 is a cross-sectional view of a joint surface illustrating a deteriorated articular cartilage on the lower joint surface.

Figure 2 is an isolated view illustrating the injection of a growth hormone and buffer solution in the joint cavity.

[0020] Like reference numerals refer to like parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0021] The present invention is directed specifically towards a method of treating inflammation and associated pain in a joint, such as one having damaged or defective articular cartilage 10. Articular cartilage 10, which is present between bones 15 at a joint 20, provides a bearing type surface for facilitated movement between the bones 15. If articular cartilage is damaged or deteriorated, as represented by reference numeral 30 in the drawings, this can result in a person's experiencing significant heat, redness, pain, swelling, stiffness and/or malalignment of the limb or joint, and can even be crippling to some individuals, such as those suffering from a trauma or other ailments which destroy the joint surface. The articular cartilage 10 is a resilient layer of tissue which covers the ends of bones 15, and it has been traditionally-assumed that once gone, it cannot be regrown or regenerated, at least until the work by the inventor hereof, some of which has been set forth in U. S. Pat. No. 5,368,051.

[0022] The method of the present invention is a significant improvement over what is known in the art for treating the sometimes excruciating pain which individuals experience in one or more of the joints of their bodies. For example, the present invention does not involve a surgical procedure, which would require some recovery therefrom, nor any type of transplantation of tissue. The method of the present invention, which is believed to offer swift relief to the heat, redness, pain, swelling, stiffness or other inflammatory symptoms experienced by individuals suffering from damaged articular cartilage in a joint, offers an improvement over the method described in the inventor's previous U.S. Pat. No. 5,368,051 by relying upon the utilization of a lower dosage of growth hormone and of an alternative buffer solution, and if desired, the addition of injectable anesthetics. The method of the present invention is thought to be effective as a result of the discovery that In addition to the metaphyseal growth plate which exists near the ends of bones and which makes the bones grow during the immature and adolescent periods, there is also an articular growth plate at the joint surface. The metaphyseal growth plate, once achieving full growth within the bone, ceases to function in an adult and disappears. The articular growth plate, however, remains intact, although growth-inactive, at the joint surface in the adult. When properly stimulated by injecting purified growth hormones in the joint, including an anesthetic if desired, as in the method(s) of the present invention, there would be no need for surgically exposing the joint nor for debriding it; the pain and inflammation associated with the damaged articular cartilage is relieved, and this is thought to be because the articular growth plate is stimulated so as to resume active growth.

[0023] With reference now to Figure 1, when an articular cartilage defect as at 30 is present in the joint of an individual, whether a hip joint, knee joint, ankle joint or other type of joint, such that it causes him or her sufficient pain to seek out medical treatment, it is preferable that the individual be required to undergo certain tests in an effort to determine whether treatment in accordance with the present invention is advisable. For example, it is preferred that the individual undergo a complete physical examination by a licensed physician, including any X-rays, MRIs, and/or other laboratory work that may be recommended to hopefully rule out the presence of serious, acute or chronic illnesses and/or whether the individual has a pre-existing excess amount of growth hormone. That is because it is preferred that such persons would not be treated in accordance with the present invention.

[0024] Turning more specifically to the method of the present invention, it is directed preferably for use on humans; however, it can be similarly effective with other animals so long as the necessary growth hormone, preferably purified growth hormone, is utilized. It is preferred that the growth hormone be species specific which means that human growth hormone would be used on humans; cattle (bovine) growth hormone would be used on cattle; and horse growth hormone would be used on horses, etc. More in particular, it is preferred that the growth hormone (known as somatotropin) utilized be identical to naturally produced growth hormones of that species. If a biologically engineered hormone alternative were to be used, it should have an amino acid sequence identical to the natural hormone. In the most preferred embodiments, the growth hormone is biologically engineered to exactly duplicate the natural hormone and to assure maximum purity, and avoid the possibility of transmitting disease. For example, if the growth hormone is to be prepared from pituitary glands retrieved from cadavers, the hormone preparation may transmit rare forms of neurological disease even though it may be highly purified.

[0025] More in particular, the method of the present invention generally comprises the steps of dissolving a quantity of growth hormone, preferably somatotropin that has ideally been biologically engineered so as to be in a purified state, in a buffer solution and then injecting the resulting solution into the joint having damage which causes an individual to experience pain or inflammation. The quantity of growth hormone to be dissolved in the buffer solution is discussed in greater detail below. The purified growth hormone is typically in the form of a pow-

der and as such, may be readily dissolved in a buffer solution. Preferably, the buffer solution has a range of pH between 5.5 and 8.3, although more preferably, the range of pH is between 6.0 and 8.0. Generally, buffer solutions include a saline solution and have a pH range of approximately 7.0 to 7.4 which is the range of biological pH. In a preferred embodiment, the buffer solution comprises a phosphate buffer which may also include a preservative. In an alternative embodiment, the buffer solution is Hank's Buffer Solution having a higher pH range of about 8.0. Other preparations of purified growth hormone may, due to their chemical composition, require buffer solutions of other ranges of pH.

[0026] The growth hormone to be dissolved in the buffer solution can be in a range of between 0.5 milligrams and 10.0 milligrams of growth hormone per milliliter of buffer solution, although a most preferred dosage of about 5.0 to 7.0 milligrams growth hormone, and ideally, 5.8 milligrams of growth hormone per milliliter of buffer solution would be used. This dosage is thought to be operative in accordance with the present inventive method for most human individuals. An alternative dosage to be administered can be more closely related to the person's and/or animal's weight, and will be in the preferred range of 0.025 milligrams to 0.249 milligrams per Kilogram of body weight.

[0027] Once the growth hormone and buffer solution have been mixed, a single dosage of the mixture is injected to the joint, as illustrated in Figure 2. The growth hormone is injected, such as by utilizing a syringe 70, into the joint space and not directly into the bone 15 or tissue. In this manner, it may flow over the entire joint surface and react initially with the tissues on the surface and then with all the vascular units 40 at the bone-cartilage interface. A portion of the purified growth hormone may be absorbed into the bloodstream after about four hours. One of the systemic effects associated with this absorption into the general circulation will be to stimulate production of stem cells in the marrow, vascular system and other areas outside the joint. The growth hormone will cause a reaction in the subchondral vascular structures so as to promote local production of endothelial derived stem cells and also to attract pleuripotential cells to the sinusoidal layer of the bone, the pleuripotential cells being collected in these vascular structures. The reaction will initiate cell layer growth at the subchondral layer, and it is believed will eventually produce enough cartilage to form additional joint surface and lead to there being an increased space between the bones of the joint being treated in accordance with the present invention. Depending on the individual patient's condition, repeated, periodical injections of the growth hormone may be required. For example, another single dosage may be injected into the joint in about four weeks, and repeated in another four weeks. Injections could be given and repeated at other time intervals, however, such as every two weeks. Alternatively, single or multiple injections can be given one day, several days, to several weeks or months apart. Such repeated injections of somatotropin or growth hormone may be necessary in situations where a patient suffers from a disease which will continuously impair or destroy the cartilage surface, or antagonize the action of the growth hormone. It is further contemplated that the injection of growth hormone according to the present invention could include the addition of chemical substances which will block or impede the antagonistic action of proteases, present in certain diseases, that might impair or prevent the beneficial action of the growth hormone within the joint.

[0028] In an alternative embodiment, the method of the present invention may comprise an additional step of mixing Lidocaine or another local anesthetic with the mixture of growth hormone and buffer solution prior to injection into the joint. In this embodiment, the amount of Lidocaine or other anesthetic to be mixed with the growth hormone and buffer solution may be anywhere from 0.5 milliliters to 10 milliliters, although preferably, about 1 to 3 milliliters will be used.

[0029] From the preceding, it is recognized that the present invention may also be considered to include a beneficial anti-inflammatory composition and/or an analgesic composition, both of which may, of course, be utilized within the previously defined methods. Specifically, the anti-inflammatory and/or analgesic composition may comprise a purified growth hormone of between 0.025 milligrams to 0.249 milligrams per kilo of a patient's body weight dissolved in a buffer solution of approximately between 1 to 10 milliliters, preferably as described with regard to the method of treatment, or a purified growth hormone of approximately between 0.5 milligrams to 10.0 milligrams per milliliter of the buffer solution, also preferably as previously recited. Further, a local anesthetic agent, anti-protease agent and/or anti-enzyme agent may be included therewith. In the case of the local anesthetic, it may preferably include Lidocain in an amount of generally between about 0.5 milliliter to 10 milliliters.

[0030] In yet another embodiment, the present invention additionally comprises a preliminary step involving treatment of the joint with an anti-growth factor. More in particular, the preliminary step involves the injection or other application of a group of agents such as anti~cytokines, anti-kinases, anti growth factors - used individually or in various combinations thereof - to a joint about to undergo -treatment for inflammation, as described previously herein. In one embodiment the injection of such agents may be made simultaneously, as in all in one step, or substantially simultaneously, with the injection of growth hormone solution pursuant to the inflammation treatment. For example, the agent(s) may be admixed with growth hormone for the purposes of the present invention. Preferably, the agent is Embrel, a commercially available anti-TNF antibody. The agent is advantageously administered in an amount of about 3mg to about 25mg, in combination with growth hor-

mone, for example by injection into the joint.

[0031] Alternatively, the joint may be preliminarily treated by making one or more intra-articular injections of such agents. Suitable agents include Embrel in a quantity of about 3 to about 25 mg from 1 to 7 days prior to subsequent treatment with growth hormone for inflammation as described herein. The injection may be repeated from 1 to about 4 times, or more. The presence of Embrei or other acents such as anti~cytokines, anti-kinases, anti growth factors - used individually or in various combinations thereof - has the effect of quieting the joint. This is believed to be due to the reduction and/or removal of the irritating activity of certain agents, e.g. tumor necrosis factor, which might otherwise impede and/or interfere with the responsiveness of the joint to subsequent treatment with growth hormone for inflammation. As such, the preliminary treatment with a group of agents such as anti~cytokines, anti-kinases, anti growth factors - used individually or in various combinations thereof - should aid in the overall success rate of the treatment with the present invention, particularly in patients having rheumatoid joints and/or rheumatoid arthritis.

[0032] In yet another embodiment, the present invention may additionally comprise the use of a lubricant, optionally added to the growth hormone solution. In particular, a lubricant such as purified hyaluronic acid or a hyaluronate salt may be used. Preferably, about 1mg to about 30mg of sodium hyaluronate is administered, about 1 to about 7 days prior to treatment of the joint with growth hormone for inflammation. Alternatively, or in addition, the lubricant may be administered in combination with and/or simultaneously with the growth hormone solution. Furthermore, a mixture of lubricant with growth hormone may be prepared beforehand, and the mixture administered. Advantageously, the lubricant and/or mixture is injected directly into the joint. The administration may be repeated from one to about four times, or more.

[0033] Since many modifications, variations and changes in detail can be made to the described preferred embodiment of the invention, it is intended that all matters in the foregoing description and shown in the accompanying drawings be interpreted as illustrative and not in a limiting sense. As examples, the present invention is also claimed in terms of a method for increasing a patient's range of motion in a joint as well as reducing the mal-alignment of a patient's arthritic joint, the latter of which can be characterized as a bow-legged deformity when the joint involved is the knee. In other words, it is the inventor's belief that the intra-articular injection(s) of growth hormone into joint(s) restores normal alignment of osteo-arthritic and post traumatic arthritic knees, such that a bow leg deformity may disappear and the leg can regain normal alignment, and further, or alternatively, that it can restore normal or nearly normal motion in both extension and flexion in osteo-arthritic and post traumatic arthritic knees or other joints. This increased range of motion can be assisted by therapeutic exercise(s), which normally, without treatment in accordance with the present invention, would be extremely painful. In many cases then, therapeutic exercises can only be carried out following treatment with the present invention in as much as the present invention reduces the pain experienced by the patient so as to permit the exercise(s) to occur at all. As another example, the inventor believes that the method of the present invention can be used to treat and/or increase the joint soaces between the vertebrae of the spine, as well. Thus, the scope of the invention should be determined by the appended claims and their legal equivalents.

Claims

1. Use of growth hormone in the manufacture of a composition for treating inflammation in a joint of a body.

2. Use according to claim 1, wherein treating the joint for inflammation comprises the steps of:

   a) dissolving a quantity of purified growth hormone in a buffer solution, and
   b) injecting a single dosage of said growth hormone and said buffer solution into said joint along the joint surface.

3. Use according to claim 2, wherein said buffer solution has a range of pH between generally about 5.5 and 8.3.

4. Use according to claim 3, wherein said buffer solution is a phosphate buffer solution.

5. Use according to claim 3, wherein said buffer solution is Hank's Buffer Solution having a pH of about 8.0 to 8.3.

6. Use according to any preceding claim wherein said growth hormone is species specific so as to be identical to naturally produced growth hormones.

7. Use according to any preceding claim wherein said growth hormone is biologically engineered to assure maximum purity and disease elimination.

8. Use according to any one of claims 2 to 7 wherein a range of 0.5 to 10.0 milligrams of said purified growth hormone is dissolved in generally about 1 to 10 milliliters of said buffer solution, the total volume of said dosage being dependent upon the weight of the individual subject being injected, and the size of the joint.

9. Use according to claim 8 wherein said dosage is a single dosage and is between generally about 0.025 to 0.249 milligrams of purified growth hormone per Kilogram of body weight.

10. Use according to claim 9 wherein about 5.8 milligrams of said purified growth hormone is dissolved in 1 to 10 milliliters of said buffer solution.

11. Use according to any one of claims 8 to 10 further comprising the step of injecting a second one of said single dosage into the joint generally about one week later.

12. Use according to claim 11, further comprising the steps of injecting a third one of said single dosage into the joint generally about one week later.

13. A Use according to any one of claims 8 to 10, further comprising the steps of injecting a second one of said single dosage into the joint generally about two weeks later.

14. Use according to claim 13, further comprising the steps of injecting a third one of said single dosage into the joint generally about two weeks later.

15. Use according to any one of claims 8 to 10, further comprising the step of injecting a second one of said single dosage into the joint generally about four weeks later.

16. Use according to claim 15, further comprising the steps of injecting a third one of said single dosage into the joint generally about four weeks later.

17. Use according to any preceding claim, further comprising the step of mixing generally about 0.5 milliliters to 10 milliliters of a local anesthetic with said mixture of growth hormone and buffer solution.

18. Use according to claim 17 wherein the local anesthetic is Lidocaine.

19. Use of a single dosage of a growth hormone in a range of 0.025 milligrams to 0.249 milligrams per kilogram of patient body weight dissolved in a buffer solution in the manufacture of a composition for increasing a patient's range of motion of a joint.

20. Use of at least a single dosage of a growth hormone in a range of 0.025 milligrams to 0.249 milligrams per kilogram of patient body weight dissolved in a buffer solution in the manufacture of a composition for correcting a malalignment in an arthritic joint of a body, such as a bow-legged deformity.

21. Use of at least a single dosage of a growth hormone in a range of 0.025 milligrams to 0.249 milligrams per kilogram of patient body weight dissolved in a buffer solution in the manufacture of a composition for increasing the space between the bone ends of a patient's joint.

22. Use of at least a single dosage of a growth hormone in a range of 0.025 milligrams to 0.249 milligrams per kilogram of patient body weight dissolved in a buffer solution in the manufacture of a composition for smoothing the surface of the bone ends of a patient's joint.

23. An anti-inflammatory composition comprising a purified growth hormone of between 0.025 milligrams to 0.249 milligrams per kilo of a patient's body weight dissolved in a buffer solution of between 1 to 10 milliliters.

24. An anti-inflammatory composition as recited in claim 23 further comprising a local anesthetic.

25. An anti-inflammatory composition as recited in claim 23 further comprising an anti-protease agent.

26. An anti-inflammatory composition as recited in claim 23 further comprising an anti-enzyme agent.

27. An anti-inflammatory composition comprising a purified growth hormone of between 0.5 milligrams to 10.0 milligrams per milliliter of a buffer solution.

28. An anti-inflammatory composition as recited in claim 27 further comprising a local anesthetic.

29. An anti-inflammatory composition as recited in claim 27 further comprising an anti-protease agent.

30. An anti-inflammatory composition as recited in claim 27 further comprising an anti-enzyme agent.

31. An analgesic composition comprising a purified growth hormone of between 0.025 milligrams to 0.249 milligrams per kilo of a patient's body weight dissolved in a buffer solution of between 1 to 10 milliliters.

32. An analgesic composition as recited in claim 31 further comprising a local anesthetic.

33. An analgesic composition as recited in claim 32 wherein said local anesthetic comprises Lidocain in an amount of generally between about 0.5 milliliter to 10 milliliters.

34. An analgesic composition as recited in claim 33 further comprising a local anesthetic agent.

35. An analgesic composition as recited in claim 33 further comprising an anti-protease agent.

36. An analgesic composition as recited in claim 33 further comprising an anti-enzyme agent.

37. An analgesic composition as recited in claim 31 further comprising an anti-protease agent.

38. An analgesic composition as recited in claim 31 further comprising an anti-enzyme agent.

39. An analgesic composition comprising a purified growth hormone of between 0.5 milligrams to 10.0 milligrams per milliliter of a buffer solution.

40. Use according to any one of claims 1 to 22, further comprising the administration of a group of agents such as anti~cytokines, anti-kinases, anti growth factors - used individually or in various combinations thereof.

41. Use according to claim 40, wherein one or more agents is administered in combination with the growth hormone.

42. Use according to claim 40, wherein one or more agents is administered prior to treatment with growth hormone for inflammation.

43. Use according to any one of claims 1 to 22, or 40 to 42, further comprising the use of a joint lubricant.

44. Use according to claim 43, wherein the lubricant is sodium hyaluronate.

45. Growth hormone and a group of agents such as anti~cytokines, anti-kinases and anti growth factors, for simultaneous, simultaneous separate or sequential use in the treatment of inflammation of a joint.

46. Growth hormone, a joint lubricant and a group of agents such as anti~cytokines, anti-kinases and anti growth factors, for simultaneous, simultaneous separate or sequential use in the treatment of inflammation of a joint.

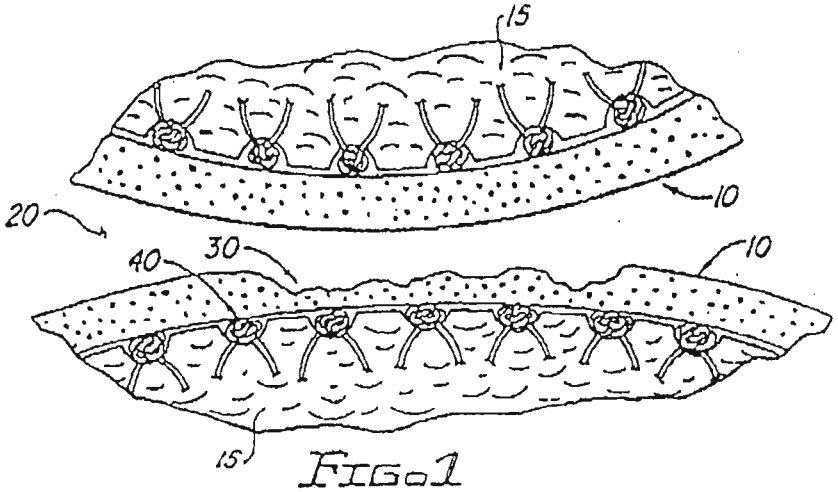

FIG. 1

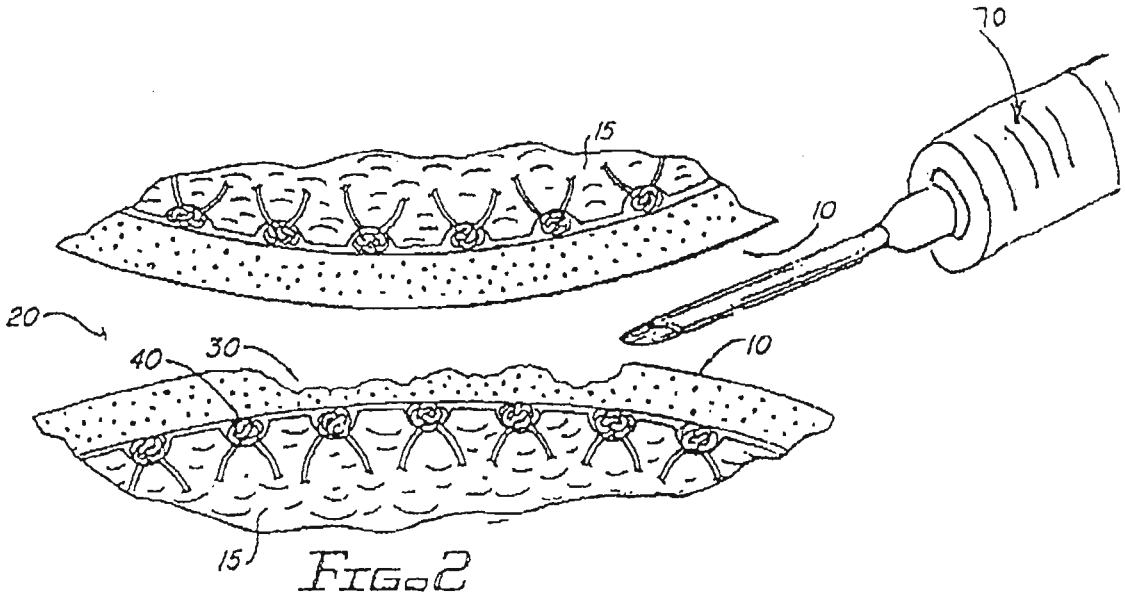

FIG. 2

Meeting c Chris

Mascia — MRI

u/s Bookings without seeing patient [illegible]

[illegible]

using back door special fast Track for personal [illegible]

outside clients without MD approval

Gymnasts – issues re testing young gymnast to come back in [illegible] [illegible] giving test results to young ✓

athletes (not their parents)

- undermining [illegible] [illegible] working [illegible] ✓

- upset lot of parents. won't come back

Utilizing facility – using facility for personal clients

on off hours

Overstepping boundaries — [illegible]

— [illegible] without MD [illegible]

EXHIBIT B

Information about Prolotherapy, Prolotherapy Treatments, Side-Effects, Injections, Research and Reviews

Knee surgery

- Prolotherapy & Knee surgery
- Knee Surgery Based on an MRI?
- Knee Injury Repair Without Surgery
- Knee Arthroscopy for Osteosarthritis
- Surgical option - Ligament
- Cartilage Transplant Surgery
- ACL Treatment Options
- CW's story - Bilateral Knee Pain
- Bilateral Knee Replacements
- Cortisone, arthroscopy, Prolotherapy
- Knee Replacement, Arthroscopy
- Knee Instability
- Delamination of cartilage
- Prolotherapy after Arthroscopy

Knee Cap pain

- Knee Cap chondromalacia patella
- Knee Cap Patella Disorders

Cartilage Repair

- Cartilage Repair in Knee Pain
- Knee Cartilage Regeneration
- Delamination of articular cartilage

Knee Replacement

- Prolotherapy - Knee Replacement
- Prolotherapy - artificial knees

Ligament damage alternatives

- MCL
- ACL Injury and Hormones
- Knee ligaments: ACL, MCL and PCL
- Estrogen and ACL Injuries
- Ligament and Tendon Laxities
- Pes Anserinus Tendons

Meniscal damage alternatives

- Knee Menical Injury
- Meniscal Injury
- Meniscus case history
- Meniscus Tear case history
- Meniscus surgery option
- Meniscal Surgery Options
- Lateral Meniscus - Case Study
- Acute Menical Tear

More knee pain articles

- Bilateral Knee Pain
- Knee Injury and Cortisone
- Prolotherapy, Diet - Golfer's Knee

Cartilage regeneration

Since the writing of this article Dr. Hauser has published his own research on the growth or articular cartilage in knees and this article is available on this website **Cartilage Regeneration in Five Degenerated Knees**

The cartilage crisis directly parallels the increase in the incidence of arthritis. There are now 40 million people in the United States with arthritis and this number is expected to grow to 60 million by the year 2020. The cartilage crisis is so bad that the number of admissions to hospitals is directly related to the number of people with osteoarthritis, as this is the third most common reason for hospital admission in the United States. Additionally, 120,000 hip replacements and an incredible 245,000 knee replacements are performed each year, making the odds one in 14 that you will get a hip or knee replaced.

Why Are We In a Cartilage Crisis?

This is not too difficult to figure out just from the figures of the number of people needing joint replacement surgery as directly correlated to the number of people who are developing arthritis, which is directly related to the number of people who have received cortisone injections, arthroscopy, RICE treatment, and anti-inflammatory medications over the past 40 years. These treatments accelerate cartilage breakdown tremendously, and thus also accelerate the arthritic process.

What is the Cartilage Crisis?

Most of the joints in the body are synovial joints, that is movable, lubricated joints which are able to provide normal pain-free movement because of the unique properties of the articular cartilage. The articular cartilage (see research paper) covers and protects the ends of the bones in joints. The knee is the largest synovial joint.

Ross Hauser, M.D.

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Ask Dr. Hauser About Prolotherapy
Call 708-848-7789

Dr. Hauser received his M.D. from the University of Illinois, Chicago; completed his residency at Loyola-Hines VA-Marianjoy Hospitals in Physical Medicine and Rehabilitation; and received his Bachelor of Science degree from the University of Illinois, Urbana-Champaign.

Dr. Hauser is one of the leading experts in the treatment of chronic pain and sports injuries with Prolotherapy. He, along with his wife Marion, have written seven books on the topic of Prolotherapy, a comprehensive book on the natural medicine approach to cancer, as well as a myriad of articles and newsletters for the general public. Read more about Ross Hauser MD

The Journal of Prolotherapy

Prolotherapy Researcdh

- Knee Injuries in the Older Athlete
- Baker's Cyst and Prolotherapy
- Swimmer's Knee Injuries
- Knee Braces
- MRI accuracy
- Loose Bodies
- Artificial knees
- Baker's Cyst

Prolotherapy and Knee Pain

- Meniscal Tears and Degeneration
- Regeneration of Articular Cartilage
- MRI - *See Knee Research Study*
- Prolotherapy research links

Prolotherapy Videos

- Anterior Cruciate Ligament Video

Platelet Rich Plasma Therapy (PRP)

- Platelet Rich Plasma Solution
- Failed Surgery, Prolotherapy, - PRP
- Labrum and Menisci Degeneration and or Tears
- PRP Case Study
- PRP Prolotherapy as a Surgical Alternativefor the athlete
- PRP (Platelet Rich Plasma) Prolotherapy Doctors
- Why Not Just Give Platelet Rich Plasma To Every Patient?

Sports Injuries

- Knee Injuries in the Older Athlete

Prolotherapy Links

- Prolotherapy Doctors
- Bone Marrow Prolotherapy
- Prolotherapy.org
- Learn about us

At the top of the knee are the massive quadricep muscles which cause the knee to extend. The hamstring muscles are at the back of the knee and cause it to flex. The knee joint has a synovial membrane, which is tissue that lines the noncontact surfaces within the joint capsule. This tissue secretes lubricating synovial fluid, which nourishes all the tissues inside the joint capsule. The knee has internal ligaments (cruciate ligaments) and external joint ligaments (collateral ligaments) which stabilize the joint, especially during movement. The knee also has menisci, pads of fibrous cartilage which help the weight-bearing bones absorb shock. The ends of the tibia, femur, and patellar bones of the knee joint are covered by articular cartilage. This is the structure that is in crisis. *(See A Retrospective Study Shows Prolotherapy is Effective in the Treatment of MRI-Documented Meniscal Tears)*

Articular cartilage allows near frictionless motion to occur between the surfaces of two bones. Furthermore, articular cartilage distributes the loads on the joint articulation over a larger contact area, thereby minimizing the contact stresses, and dissipates the energy force associated with the load.

Articular cartilage is made of specialized protein structures, called Proteoglycans, water, and collagen. The cells (chondrocytes) of articular cartilage are responsible for the synthesis of both the collagen and proteoglycans that make up the cartilage and have the ability to synthesize all the various components of the specialized proteins that make up the proteoglycans.

This ability of these chondrocytes (see research paper) to replicate is really the key question when considering the potential of cartilage to proliferate or to repair itself. It has been shown in studies on adult human cartilage that there is no decrease in cell counts, even in individuals of advanced age. This fact alone suggests that chondrocytes have the ability to proliferate and repair. Additionally upon certain injury such as mild compression, osteoarthritis, or lacerative injury, the chondrocytes are capable of mitotic division, indicative of growth and proliferation.

The notion of damaged cartilage having no regenerative properties is responsible for many people being subjected to

arthroscopies with subsequent joint replacements. This falsehood or myth occurred because healthy cartilage cells have very little, if any, mitotic activity, thus very little or no ability to proliferate.

A bulk of research on articular cartilage regeneration was performed in the 1980s and 1990s. Dr. H.J. Mankin discovered that the chondrocytes reaction to injury was to change into a more immature cell, called a chondroblast, which was capable of cell proliferation, growth, and healing. This key fact is vital to understanding the power of Prolotherapy in proliferating cartilage regrowth.

The Role of Prolotherapy in Cartilage Growth

Prolotherapy involves the injection of substances, such as hypertonic dextrose, sodium morrhuate (extract of cod liver oil), various minerals, Sarapin (extract of the pitcher plant), and various other substances including Growth Hormone, which act by stimulating the structures to repair. (The actual substances injected depend on the individual case and the physician.) The current theory of cartilage regeneration is that this irritation acts in the same mechanism as above in inducing the chondrocytes into the chondroblastic stage of development capable of proliferation and repair. The numerous patients, who had no cartilage or were set for hip/knee replacements who never needed them because of Prolotherapy, support this fact.

Can It Be Proven That Prolotherapy Regenerates Knee Cartilage?

It is impossible to do a double-blind study on Prolotherapy because even an injection of sterile water under the skin has a beneficial therapeutic effect. Even if no injection was given on one side, as the control, sticking a needle into a painful area is known to have a beneficial effect (this treatment is called acupuncture). It is very difficult to prove using a traditional scientific model, that Prolotherapy cures chronic pain, sports injuries, and regenerates cartilage tissue.

One Prolotherapy doctor trying to validate the treatment of Prolotherapy is K. Dean Reeves, M.D., Physical Medicine and Rehabilitation Specialist, in private practice in Kansas City, Kansas. He has just completed three double-blind studies on using 10 percent dextrose versus water injections on

finger/thumb arthritis, knee arthritis, and anterior cruciate ligament injured knees. Injections were given every two months of dextrose or water. After three injections, all patients were given the dextrose proliferant for three more injections. In the knee studies, only one intra-articular (inside the joint) injection was given per knee at each session. As of this writing, the x-ray readings at one year had just been completed. In the finger/thumb arthritis study there was a 53 percent improvement in pain, and eight degrees of improvement in flexibility. In the knee arthritis study there was a 44 percent improvement in pain, 63 percent improvement in swelling, and a 14-degree improvement in flexibility. There was an 85 percent reduction in knee buckling episodes. The loss of cartilage not seen on x-rays by one year and bone spur measurements showed improvement. Of interest was the fact that those without cartilage did nearly as well. In the knee laxity (ACL) study, pain improved 27.5 percent, swelling by 51 percent, and knee buckling episodes by 54 percent. X-ray studies at one year showed improvement in two measures of bone spur and near-significant improvements in thickness of cartilage in the knee. One should remember that this study involved just one knee injection per session and articular cartilage growth was seen. Typically in actual practice, a person with laxity in the knee ligaments may get 20 injections per visit. Dr. Reeves summarized the findings as "...these double-blind studies with objective and measurable endpoints all show that simple injection of arthritic fingers or knees, or knees with ACL laxity, with non-inflammatory levels of osmotic stimulants can bring about favorable responses in pain, flexibility, and x-ray findings."

Cartilage Regeneration with Human Growth Hormone

Despite the majority of Orthopedic Surgeons doubting that cartilage can be regenerated, one physician in their own ranks has shown that cartilage growth is possible. Alan Dunn, M.D., is an orthopedist in private practice in North Miama, Florida, who has been studying cartilage regeneration for 30 years. His innovative approach involves the injection of Human Growth Hormone into the deteriorated joint. He reports, "In the rabbit studies that I conducted, just one injection grew back the whole patello-femoral surface of the knee in five to six weeks. These studies were biopsy confirmed."

He is currently conducting a study on human knees using

monthly human growth hormone (HGH) injections into knee joints with cartilage deterioration. Dr. Dunn says, "Over half of the knees show major cartilage growth, and most of the rest have a good result. The most amazing findings have been the near-complete relief of pain in these degenerated knees." Dr. Dunn has been giving a total of three HGH injections into the knees at monthly intervals.

Ask Dr. Hauser About Prolotherapy

There is no known cure for arthritis. Prolotherapy and nutritional supplements can help alleviate, reverse, or end arthritic pain by treating an underlying cause that contributes to degenerative disease, ligament laxity. Strengthening ligaments and other connective tissue can help prevent bone on bone arthritis from developing.

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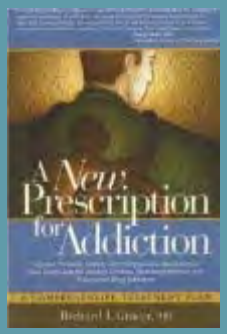

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Resources: Articles

Treatment of Degenerative Arthritis with Human Growth Hormone either with or without Intraarticular Ozone and Regenerative Injection Therapy

Richard Gracer, M.D.

Degenerative arthritis is a common and often disabling condition that plagues many of us as we age. The most commonly affected joints are the knee and the hip, although the other joints can also be involved.

As we age, the ligaments can become lax. This can be caused by either even a minor injury or by the stress of daily use. At the same time the cartilage gradually loses water content making it more rigid and therefore more vulnerable to damage. The cartilage lining the joints is gradually worn down causing pain and limitation of motion.

The most common treatment for this condition is the use of painkillers, especially non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, naproxen, and more recently Celebrex and the other COX-2 selective medications. These drugs alleviate pain, but do nothing to mitigate the underlying cause and may actually accelerate the joint degeneration by allowing increased use and therefore stress on already damaged structures. They may also slow down healing because the inflammatory process is part of the healing process.

Intraarticular injection of corticosteroids is a common and effective treatment for degenerative joint pain. These steroid hormones are a powerful anti-inflammatory and can produce pain relief that can last up to several months. It was thought that as they decrease scarring and can inhibit healing that they would also accelerate cartilage destruction in weight bearing joints(the hip and knee), especially with the increased joint use that would result from the pain reduction produced by the treatment.

A recent two year study of patients with knee arthritis showed that there was significant pain relief and no increased cartilage destruction in the steroid treated group, compared to a control group that did not receive steroid injections. Patients were not followed more than two years and hips were not studied. Therefore, while these injections are a viable option for pain relief, they should be considered only for short term treatment as they do not help the underlying pathology and may accelerate joint destruction.

Another treatment is the injection of hyaluronic acid preparations into the joints on a weekly basis from three to five times. The major brands available are Hyalgan, Synvisc, and Starpurz. These injections mimic the natural joint fluid, increasing lubrication thereby decreasing pain. These are effective in some patients, but the results are usually temporary as there is no change in the underlying joint condition.

When the pain is uncontrollable and the cartilage is gone the joints are replaced. These artificial joints have become more and more durable and sophisticated in the past few years, but they have a finite life and therefore are not recommended for middle aged patients. Many sufferers are left with few alternatives and a severely curtailed lifestyle.

Western conventional medicine does not treat the actual underlying problems, ligament laxity and the dehydration and wearing of the cartilage. The body

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created these connective tissues and these same processes can rebuild them.

Effective treatment of this condition should be aimed at slowing down the degenerative process and correcting the joint laxity, as well as stimulating cartilage growth. In order to do this several areas must be addressed:

1. Nutrition is the foundation of the whole treatment regimen. It is paramount that the body be able to produce the ligament and cartilage that will repair the damaged and /or worn joint.
2. The ligaments must be tightened. Joint laxity is often the original cause of the joint degeneration. A small ligament sprain can set up abnormal stresses that can lead to severe joint degeneration years later.
3. The cartilage must be regenerated. The joint cannot function properly without a cartilage lining. The cartilage does not have to be as thick as it was originally, but even some increase in thickness can cushion the joint, allow increased range of motion, and reduce pain. (The cause of joint limitation is often due to boney spurs. This motion reduction will persist after treatment.)
4. There must be a physical rehabilitation program to maintain joint motion and muscle strength.

The treatment program consists of the following components:

1. Nutritional supplementation including glucosamine sulfate, chondroitin sulfate, MSM, high dose vitamin/mineral supplementation with high dose vitamin C, and pharmaceutical grade fish oil. Nutritional counseling may also be suggested in specific situations.
2. Regenerative injection therapy(prolotherapy) for ligamentous laxity if needed. This is performed usually every two weeks from four to six treatments depending on the underlying lesion and joint involved. RIT is the injection of a mild irritating solution onto ligaments and tendons to stimulate the normal healing process.
3. Ozone/oxygen mixture injected into the joint at the time of the RIT. Ozone is used extensively in Italy and Germany for many medical conditions. Ozone is a powerful oxidizer which when injected rapidly dissolves in the intraarticular fluid and then reacts with whatever molecule it encounters, creating free radicals. These are easily quenched by the body's antioxidant systems. This causes the release of locally acting hormones called cytokines which start and maintain the healing and repair processes. This ozone therapy can be repeated regularly during the treatment period.
4. Intraarticular injection of human growth hormone (HGH). HGH is injected into the joint every one to two weeks. This stimulates bone cells to change into cartilage producing chondrocytes by a process called "morphoangiogenesis". This has been researched and developed by Allan Dunn, MD, an orthopedic surgeon in Florida. He has extensive experience and has reported excellent results. (See his website is www.IAGH.com for his specific success rates and other data). Since the HGH molecule is very fragile this injection must be performed without any other treatment at the same time.
5. The best results require avoiding weight bearing during the cartilage regrowth. Some physicians have reported good outcomes without this and there has been research that shows that RIT caused cartilage regrowth without HGH with normal weight bearing. (see www.getprolo.com for more specific data on this research by Reeves)

This treatment program combines three therapies that each promote cartilage regrowth and joint integrity. They are complementary and should be synergistic.

Some patients who have preserved cartilage, but ligamentous laxity and/or cartilage damage do not need HGH, but will respond to the RIT/Ozone treatment regimen alone.

Please read the information that we have on RIT and medical ozone and feel free to ask any questions about your specific condition.

Allan R. Dunn, M.D.
Fellow American Academy of Orthopedic Surgery
Diplomate American Board of Orthopedic Surgery

About Dr. Dunn
Curriculum Vitae
Contact Info

"EXTRAORDINARY"

Is the opinion of a noted professor of Orthopedic Surgery, Emeritus, at Harvard University.

IAGH means Intra-Articular Growth Hormone Treatment

IAGH can help you AVOID TOTAL JOINT SURGERY

IAGH is a Stem Cell Method that grows real Joint Cartilage. It does this by regrowing the fetal cartilage skeleton in an adult's joint.

This is important because because real joint cartilage is a remnant of the fetal cartilage skeleton! So to replace real joint cartilage you need to re-grow a portion of the fetal skeleton. That would seem impossible. And it was until Dr. Dunn discovered IAGH, the discovery the Harvard professor called extraordinary. IAGH is the only method which can regrow that portion of the fetal skeleton which is articular cartilage. All the other attempts to repair cartilage cannot.

These other attempts at repair are MICRO-FRACTURE, DRILLING, MOSAICPLASTY, CARTICEL AND CARTICEL IN MATRIX. THESE OTHER METHODS PRODUCE FIBROCARTILAGE. UNFORTUNATELY FIBROCARTILAGE LASTS ONLY A SHORT TIME AND IS NOT A GOOD JOINT SURFACE.

IAGH PRODUCES REAL JOINT CARTILAGE. IT COULD LAST AS LONG AS THE ORIGINAL CARTILAGE.

IAGH SCIENCE: **The IAGH process rejuvenates adult blood vessels in your joint to form fetal vessels. These fetal vessels produce your own (Autologous) stem cells which then form cartilage cells (Chondrocytes). These new cartilage cells produce a new cartilage surface in your joint. This process has been published in a peer reviewed journal: "Morphoangiogenesis - a Unique Action of Growth Hormone", Allan R. Dunn, M.D., Microvascular Research Vol. 63 pages 295 - 303, 2002.**

IAGH patients have osteoarthritis of the knees, hips, ankles, shoulders, or elbows, wrists and thumbs. Some IAGH patients have rheumatoid arthritis. All

patients are placed on a protocol which includes intra-articular injections of HGH and an exercise program. Patients need to avoid weight bearing on hips, knees and ankle during IAGH treatment.
Patients with rheumatoid arthritis require concurrent treatment with an anti-TN Factor, such as Enbrel FOR SUCCESSFUL RESULTS IN RHEUMATOIDS.

Questions patients frequently ask are answered here:

1. **What is the success rate of IAGH treatment?**
   Based on significant measurable increase in motion, decrease of pain, and increase of joint space, the following percentages give some idea of the success rate:
   - Ankles 95%
   - Knees 86%
   - Hips over 50%
   - Elbows 95%
   - Shoulders 75%
   - Thumbs 75%

2. **What are the beneficial effects of IAGH treatment?**
   Decrease or complete abatement of pain, swelling, heat and stiffness in the treated joint. Measurable increase in the space between the bone surfaces. The bone on bone condition often improves and space re-appears - up to a 4 millimeters between the bones. Several patients have been followed over five (5) years, and their symptoms have not recurred. In several cases of osteoarthritis of the knee, the bow-legged deformity was reversed and the alignment of their knees WAS restored to normal.

3. **Do you need to continue receiving IAGH injections?**
   Some patients require booster injections of IAGH ONCE A YEAR OR ONCE EVERY 2 YEARS, OR NOT AT ALL.

4. **What are the side effects of the IAGH treatment?**
   There were a few side effects and they were mild and reversible. There has RARELY been pain or swelling at the injection site.
   TOTAL JOINT SURGERY CAN HAVE SERIOUS COMPLICATIONS SUCH AS INFECTIONS, DEEP VEIN THROMBOSIS, PULMONARY EMBOLISM, and DEATHS.
   None of these complications occur with IAGH treatment .

5. **What is the COST OF IAGH TREATMENT:**
   IAGH TREATMENT COSTS ¼ THE COST OF TOTAL JOINTS!! A TOTAL KNEE CAN COST OVER $35,000.00. IAGH TREATMENT OF THE SAME KNEE COULD COST LESS THAN $10,000.00 WHICH INCLUDES ARTHROSCOPIC SURGERY, ANY MEDICATIONS, AND rHGH.

6. **What happens if the treatment does not work?**
   Nothing. You are no different than when you started treatment. No patient was made worse by IAGH treatment. Nothing happens to your joint that would prevent a total joint replacement.

Dr. Dunn does not folow or understand the FDA position that "of label" use is not permitted. But this is advisory that Dr. Galea had seen and relied on

7. **WHAT IS rHGH?**
   rHGH is X pure HUMAN growth hormone approved by the FDA. rHGH means recombinant HUMAN GROWTH HORMONE. It is made in laboratories. Several well known pharmaceutical companies manufacture rHGH. rHGH is pure and free of all viruses. rHGH has been manufactured for several years and is approved by the FDA for several uses, such as making short children grow to normal size. It has not yet been FDA approved for injection in joints, which is an "off-label" use.

8. **WHAT IS "OFF-LABEL" USE OF A MEDICATION?**
   The use of rHGH to grow new cartilage in joints is an "off-label" use. This means that an FDA approved hormone can be used for other than the FDA approved uses if the physician believes the medication is beneficial for a patient. Dr. Dunn believes that IAGH injection is very beneficial for patients with arthritis and joint injuries.

Treating Hips with IAGH:

Dr. Dunn is constantly IMPROVING the treatment of arthritic hips. He TREATS impingement OF THE HIP, NOW CONSIDERED A MAJOR cause of osteoarthritis of the hip. HE has started a series of ARTHROSCOPIC procedures to remove the causes of impingement and conserve the natural tissues of the hip joint. MERELY conserving the

tissue does not regrow ANY cartilage that has already been lost. Dr. Dunn HAS THEREFORE added IAGH treatment to regrow the cartilage that was damaged by impingement. HE CONTINUES to preserve the natural tissue and avoid total joints. His "BiologicArthroplasty" WITH IAGH is a 21st Century treatment.

THE DISCOVERY OF IAGH

Allan R. Dunn, M.D. is an board certified Orthopedic Surgeon, AND RESEARCH SCIENTIST. HE discovered THE IAGH method to regenerate articular cartilage in 1965. After many years of research on laboratory animals to demonstrate the efficacy and safety of the IAGH method, Dr. Dunn, in 1998, started to treat patients with arthritis OF THE KNEE in an FDA approved study.
Every patient who has come for IAGH treatment has moderate to advanced arthritis and they have been told they need a joint replacement. They want IAGH treatment in order to avoid total joint surgery. Most patients are happy with their results after IAGH treatment BECAUSE THEY no longer NEED total joint surgery. MOST patients return to normal activities.

PUBLICATIONS:

Morphoangiogenesis: A UNIQUE ACTION OF GROWTH HORMONE in Microvascular Research 63:295-303,2002; this website IAGH.com; 2 U.S. patents and 2 European multination patents). Call our office and speak to Susan who can answer your questions.

MORPHO-ANGIOGENESIS

Morpho-angiogenesis is a unique benign action of growth hormone discovered by Dr. Dunn. He lectured on his discovery at Harvard University Medical School October 4, 2001. Morpho-angiogenesis causes rejuvenation of adult blood vessels to form fetal blood vessels which produce stem cells.
The IAGH method works because it utilizes this unique action of growth hormone. This action is a growth hormone dependent form of angiogenesis which leads to articular cartilage regeneration. Regular angiogenesis is a benign process in which new blood vessels develop and help produce new tissue. It occurs, for instance, after your skin is cut. In regular angiogenesis NEW BLOOD VESSELS develop from existing blood vessels. Morphoangiogenesis is different because it forms structures AND BLOOD VESSELS. These new structures have one special function - which is to produce stem cells followed by production of new cartilage cells. Because THE MORPHOLOGY (anatomical structure) of the vessels has changed, Dr. Dunn gave the process a special name, Morpho-angiogenesis. These new structures are IDENTICAL to the structures which produce cartilage in the fetus.

FETAL SURGERY - produces scar-free healing!

Developmental pre-natal healing

When you understand fetal healing of skin, muscle and cartilage, you will better appreciate the IAGH method. Scar does not occur in fetal surgery because healing follows the Developmental Cascade, where inflammation is absent. The results of fetal surgery dealing with skin and muscle have never been transposed into adults.
Fetal healing of cartilage has been transposed to adults, and is a major step forward in arthritic treatment - IAGH.

POST NATAL HEALING:

The other form of healing is the POST NATAL HEALING. It is the familiar result of all surgeries now, FOR EXAMPLE- the appendix scar. This form of healing is ALWAYS associated with inflammation. and ALWAYS produces scar IN SKIN, and scar - fibro-cartilage IN JOINTS.

Summary:

IAGH Healing

IAGH healing follows the Developmental Cascade. There is no inflammation. Healing with IAGH grows new cartilage with no scar (articular cartilage). All the other methods to repair cartilage follow the POST-NATAL Cascade and THEY produce scar - fibrocartilage.

- **IAGH IS AT THE CUTTING EDGE OF MEDICAL SCIENCE.**
- **IAGH UTILIZES YOUR BODY'S OWN STEM CELLS TO REGROW ARTICULAR CARTILAGE.**
- **THE IAGH PROCESS IS SCIENCE-BASED FOLLOWING 30+ YEARS OF RESEARCH.**
- **IAGH IS A PROVEN ALTERNATIVE TO TOTAL JOINT REPLACEMENT**
- **IAGH IS PATENTED IN THE U.S.A. & EIGHT EUROPEAN COUNTRIES.**

IAGH is the first instance where fetal healing has been transposed to the treatment of adults with arthritis. IAGH is the "Gold Standard" OF CARTILAGE HEALING.

Life Extension Magazine

LE Magazine May 2000

COVER STORY

Doing Away with... ARTHRITIS

An innovative procedure involving human growth hormone stimulates cartilage growth and joint mobility

by Melissa Block, M.Ed.

Current statistics show that 43 million Americans have arthritis. Swollen, painful joints compromise quality of life for 38% of men and 54% of women over the age of 65. It is estimated that 15% of the U.S. population has some form of arthritic disease, and that the overall cost of the disease amounts to 1% of the gross national product. Some arthritis patients are in constant pain, day and night; others have milder pain but still can't participate in the activities they enjoy because of loss of mobility and threat of worse discomfort. The drugs that have been developed to treat arthritis only manage symptoms, and do little to stop the degeneration of cartilage caused by the disease. When a joint threatens to deteriorate completely, orthopedic surgeons can repair or replace it-but replacement parts wear away or loosen over time and often need to be operated on again. Glucosamine sulfate, a component of cartilage, has been shown to ease pain and possibly slow progress in arthritis. Still, these remedies work slowly and are not effective for everyone. Much work still needs to be done on two new experimental therapies, hyaluronic acid (Synvisc) injections and cartilage transplants. Millions of people who have found no reliable relief from their pain and debility continue to wait for a cure. Allan Dunn, M.D., an orthopedic surgeon in private practice in North Miami, Florida, may have the answer. Since 1965, he has been working on a novel method for the treatment of degenerative cartilage diseases: the injection of human growth hormone directly into affected joint spaces.

All about the doctor

Dr. Allan Dunn attended medical school at the New York State Downstate Medical Center, where he worked at the famous Kings County Hospital. There, he was exposed to uncommon, esoteric, even bizarre medical cases-patients with problems that, in other training programs, would come up only as a footnote in a medical text. Upon graduation from medical school, he was accepted for a one-year medical internship at the highly sought after Montefiore Hospital in the Bronx. He spent a second year at Montefiore as a general surgery resident. From there, he moved on to 3 1/2 years of residency in orthopedics at the Hospital for Special Surgery at the Cornell Medical Center, the top training program for orthopedic surgery in the nation. Today, he counts himself as one of the rare physicians in private practice who also engage in ongoing medical research. Dr. Dunn also finds time in his tight schedule to hone his skills as a classical violinist. When asked how he can do it all, he answers, "When you want to get something done, ask the busiest man in town."

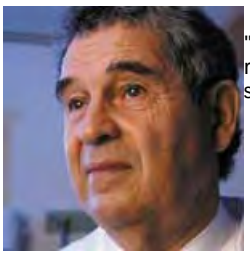
The growth hormone-cartilage connection

Dr. Dunn's development of IAHG (IntraArticular Growth Hormone) began with his study of acromegaly, a disease caused by oversecretion of growth hormone. Acromegaly is usually caused by a benign tumor that grows in the pituitary gland. The tumor stimulates the gland to secrete far more growth hormone than is required in adulthood. Excess growth hormone causes the expansion of cartilage within the joints of the fingers and toes, as well as on the forehead and chin. Fingers and toes grow longer and thicker and the forehead and chin protrude. Dr. Dunn reasoned that if growth hormone had this kind of effect on cartilage that normally stopped growing in late adolescence, it could be injected into joints to promote the growth of cartilage that had deteriorated due to arthritis.

Bone and joint Development

One of the major functions of growth hormone, during the two-decade-long transformation from embryo to adult, is to increase the length of all bones. Virtually every bone in the body starts out as cartilage, a spongy, flexible form of

connective tissue that slowly mineralizes and hardens to become bone. If you were to look at the femur (thigh bone) of a small child, you would find a short length of hard bone at its center, with softer cartilage discs-growth plates-at either end. The bone grows longer as growth hormone stimulates the growth of new cartilage in the growth plates. Behind the new growth, the cartilage skeleton mineralizes and turns to bone. At adulthood growth hormone secretion wanes, the bones stop lengthening, and the growth plates on the ends of the bones disappear. A thin layer of cartilage (about one-eighth of an inch) remains, covering the bone ends and providing cushioning and lubrication, especially in the fingers, toes, elbows, ankles, knees, hips and shoulders. This articular cartilage allows smooth, frictionless movement of the joints. Over the years, excessive wear and tear from repetitive tasks, bad posture, injury or athletics can wear down those thin cushions and expose the hard, bare bone ends to direct friction and pressure. Inflammation and arthritis pain are usually next in the progression of events.



"I'd like to see growth hormone injections as first-line therapy, to try to restore cartilage and joint mobility before resorting to invasive and risky surgery."

New findings on cartilage growth

The first step toward development of a scientific rationale for intra-articular (within the joint) growth hormone injections was to discover exactly how growth hormone stimulates the growth of cartilage. It has been known since the 1930s that it has this effect, but the exact physiological chain of events has proved difficult to discern. In textbooks on orthopedics, it is stated that cartilage is avascular (contains no blood vessels). This theory is used to explain the fact that damaged cartilage regenerates either slowly or not at all. With the use of fluorescent antibody markers and other special techniques, Dr. Dunn found that the cartilage surface has a previously undiscovered, specialized microvascular system, consisting of tiny blood vessels that fold in on one another in loops and swirls. The cartilage vessels bear a strong resemblance to the vascular loops called glomeruli, which are found in the kidneys. This resemblance inspired Dr. Dunn to dub these vascular cartilage structures Glomeruloids. While they may look alike, these two types of vessels have entirely different functions. In the kidney, the glomeruli filter wastes from the blood to produce urine. At the ends of bones, Glomeruloids produce cartilage cells. During infancy and childhood, when growth is rapid, stem cells-immature cells formed in the bone marrow and the linings of blood vessels-are moved to the growth plate through the Glomeruloids. Within these cartilage vessels, stem cells are transformed into cartilage cells. They then pass into the growth plate or the joint surfaces. An understanding of the presence and function of the glomeruloids is essential to the understanding of how IAGH stimulates the restoration of cartilage in arthritic joints. Because of the enormous cost of the research that would be required to overturn the standard beliefs about cartilage regeneration, however, Dr. Dunn has not had the opportunity to publish these findings in major medical journals.

Clinical applications

Several studies on isolated cartilage and on the joints of rabbits and dogs have shown that cartilage rapidly grows when exposed to growth hormone. Dr. Dunn's research has been designed to illustrate that this effect is due to direct growth hormone stimulation of Glomeruloid formation. In one of his experiments, all cartilage and vascular tissue was scraped from the knees of large, mature adult rabbits, leaving only the bare bone ends. After the surgery, a single dose of growth hormone was injected. In only a matter of days, hundreds of thousands of new Glomeruloids sprang up on the exposed bone surfaces in the joint. Once the Glomeruloids have formed, claims Dr. Dunn, "their only function is to produce cartilage cells." Growth hormone also increases production of collagen, a strong, fibrous connective tissue that attaches cartilage to bone and provides a framework for the matrix. Matrix is the gelatinous, resilient part of cartilage, and its production, too, is increased by growth hormone. Cells called chondrocytes manufacture the matrix. Local administration of growth hormone causes a local increase in insulin-like growth factor I (IGF-I), which sends a message to the chondrocytes to build more matrix. IAGH gives the body the cues it needs to set the cartilage growth process in motion. Stimulation of cartilage regeneration with growth hormone reproduces the same environment in which joint tissues grow during childhood. It is a completely natural therapy.

IAGH success stories

While an understanding of the physiological mechanisms is important, the real test is how well the treatments work. Normal, structurally sound cartilage has been restored with local application of growth hormone in both animal experiments and in Dr. Dunn's patients. Dr. Dunn has successfully treated 35 patients with IAGH thus far. Dr. Dunn's patented procedure entails three to six separate injections in the affected joint. Between injections, x-rays are taken to monitor cartilage regrowth. The regrowth is visible on the x-ray as increased space between the ends of the bones. Patients have consistently shown an increase from zero space to about four millimeters, a difference that can transform a nearly crippled person into one who can move again without stiffness and who can sleep through the night without waking in pain. One young patient went from being debilitated by knee pain to complete healing, which allowed him to return to his sport of pole vaulting. Another was amazed to find himself well enough to hike up Mt. St. Helens and back with no symptoms in his knee. Patients followed for up to 16 months have had no recurrence of "water on the knee," pain, swelling or heat in treated joints. They continue to improve. Some previously bowlegged patients have even reported that their knees became straighter following IAGH! The procedure has been performed on hips, knees, ankles, shoulders and elbows. Dr. Dunn hopes to soon conduct a study on IAGH for deteriorated spinal discs. The cost of growth hormone is an obstacle for many, and it is a new therapy that will require continual refinement, but the results Dr. Dunn has achieved so far are certainly impressive. Dr. Dunn does not believe that growth hormone will be a substitute for total joint replacement surgeries in all cases. He would, however, like to see growth hormone injections as first-line therapy, to try to restore cartilage and joint mobility before resorting to invasive and risky surgery.

The cost per injection of IntraArticular Growth Hormone (IAGH) is $375. Usually, three

injections are suggested. For more information on IAGH, please contact Allan Dunn, M.D. in North Miami Beach, Florida, at (888) 848-6534.

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THE GROWTH FACTOR BASIS OF PROLOTHERAPY

DAVE HARRIS, M.D.

For many years, the positive effects of Prolotherapy were thought to be mainly based on the concept of Inflammation and minor damage induced by the injection of irritating solutions, with subsequent healing of the injured areas. The benefit of solutions containing strong alcohol solutions, ground-up pumice stone, and other such recipes suggest that this is indeed one of the mechanisms of the strengthening and healing response seen with Prolotherapy.

In recent years, it has become clear that much of the benefit also comes from the stimulation of the release of growth factors in the region being treated. Some factors shown to be involved in growth and repair include Human Growth Hormone, Insulin-like Growth Factors I-IV, Transforming Growth Factor Beta, Epidermal Growth Factor, Basic Fibroblast Growth Factor, Platelet Derived Growth Factor, and undoubtedly many others. These have been shown to be released during prolotherapy treatments and appear to be the main basis for repair.

It has been shown that elevating the concentration of Glucose (sugar) by 0.5% in the fluid surrounding the fibroblasts induces the DNA machinery to release numerous factors such as those mentioned above.

The healing effect is a graded, controlled reaction producing repair of the weak and damaged connective tissue. When properly applied, Prolotherapy does not induce scar formation. The bonds are stronger, healthier, and thicker than before treatment, and with each treatment continue to strengthen, until the healing is complete and the pain resolved.

Human Growth Hormone (HGH) has been successfully injected into the joint to induce growth of cartilage. In our experience of approximately 30 patients, with knee, hip, and shoulder pain, over 50% of the patients have substantial improvement in pain. There is x-rays and MRI evidence of improved joint spacing in some patients. We reserve this for our patients who do not respond adequately to standard Prolotherapy solutions. We have seen no significant adverse effects from Prolotherapy in general in our practice experience of over 1000 patients, and Prolotherapy with HGH appears to have similar safety to

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date. Since Prolotherapy routinely greatly benefits more than 80% of our patients, HGH is not used a great deal, but when these efforts are combined, we see that approximately 90% of our patients with Osteoarthritis, ligament strain, and tendinosis have substantial improvement.

The evidence suggests that we are entering a new realm of Prolotherapy in which additional factors will be discovered that improve upon the excellent results and low risk of Prolotherapy.

PROLOTHERAPY NASHVILLE
SOAR FREE OF PAIN
THE SOUTHEAST'S PREMIERE PROLOTHERAPY PRACTICE

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PREMIERE PROLOTHERAPY
PRACTICE.

WELCOME TO PROLOTHERAPY

COST EFFECTIVE
NONSURGICAL
LOW RISK
NATURAL
HIGHLY EFFECTIVE

- Most joint pain, including neck and back pain, is caused by damaged, unhealed ligaments and tendons.
- If other abnormalities are present--... disk problems, cartilage problems, bone spurs, etc., pain may still be arising from damaged, unhealed ligaments and tendons.
- Symptomatic connective tissue damage is often impossible to detect on imaging studies, but easy to detect on physical examination.
- Prolotherapy strongly triggers the healing process in damaged, unhealed ligaments, tendons, and cartilage.
- 'Conventional treatments', including anti-inflammatory and steroid medication, only mask the pain and may further reduce your ability to heal.
- Prolotherapy is the only therapy which successfully treats the underlying cause of most joint pain.
- Prolotherapy is over 80% successful in curing joint pain due to damaged connective tissue. Prolotherapy may be your solution!

Symptoms and findings associated with damaged, unhealed ligaments and tendons:

1. Are not capable of full load-bearing.
2. Cause pain when used.
3. May cause pain at rest, or chronic pain.
4. May cause referred pain, numbness, tingling, burning, or aching which is felt some distance from the damaged structure.
5. Produce muscle malfunctions - tightness, spasm, trigger point formation, or weakness.
6. Result in abnormal mobility of bones in the joints.
7. Cause unstable joints.
8. Result in abnormal wear of cartilage.
9. Result in disk damage or rupture.
10. Result in arthritis and bone spur formation.

If you have chronic problems due to damaged, unhealed ligaments and tendons, these problems will not resolve until the connective tissue heals to normal structural integrity.

You do NOT need expensive tests to identify damaged, unhealed connective tissue structures.

You Do need a complete history and a thorough physical exam to locate these damaged structures.

The connective tissue healing process:

1. Is a very time limited process, lasting about six weeks.
2. Begins with immune cells and platelets releasing chemicals which summon and activate repair cells.
3. Repair cells (fibroblasts and chondroblasts) then make new tissue to repair the damaged structure for about six weeks.
4. 'Scar tissue' is not formed-instead these cells actually make new ligament, tendon, and cartilage.
5. Supplements, vitamins, anti-inflammatory and steroid medication, exercise, manipulation, acupuncture, physical therapy, ice, heat, and rest DO NOT trigger the healing process.
6. Prolotherapy stimulates white blood cells and/or platelets to release a group of chemicals known as 'growth factors' which trigger the body's strongest healing system.
7. Prolotherapy is the only therapy that strongly triggers the body's connective tissue healing process.

When ligaments and tendons heal, pain stops. Read Dr. Johnson's Paper regarding Connective Tissue Damage Syndrome

Even severely damaged structures and broad areas of injury usually respond well to Prolotherapy.

Maximizing your results:

- Prolotherapy results depend on your body's healing system.
- To maximize your results, we assess your overall medical condition, medications, and nutritional status, making recommendations as necessary.
- Hormone balance is important for healing. At times hormone testing and BioIdentical Hormone therapy are recommended.

The Trigger for Healing:
Proliferant Solutions

Traditional Solutions:
My standard solution, proven effective for over 50 years, uses concentrated Dextrose (sugar), Lidocaine (local anesthetic), and Sarapin (long-acting natural anesthetic).

Alternative Solutions:
In different locations and situations, proliferant additives or alternatives are used. These include Human Growth Hormone, Sodium Morrhuate, and other options. Dr. Johnson will work with you to develop a treatment that will maximize your success.

Future Solutions:
At Prolotherapy Nashville the future is already here. Dr. Johnson was one of the first practitioners in the country to use Platelet Rich Plasma (PRP) as a Prolotherapy treatment option. To use PRP, the platelets and white blood cells (both of which contain the growth factors that trigger the healing process) are removed from a sample of the patient's blood. This concentrated solution (PRP) can then be used to treat a variety of kinds of damaged structures - including ligaments, tendons, cartilage and fibrocartilage (such as the meniscus and labrum). Dr. Johnson has vast experience using this treatment for a variety of conditions.

At Prolotherapy Nashville we offer you the best of the past, the present, and the future.

The Prolotherapy Treatment:

At Prolotherapy Nashville we employ an integrated approach to treatment that minimizes the discomfort of treatment, and optimizes your healing capacity.

Prolotherapy involves injecting damaged structures. Therefore, the treatment is somewhat uncomfortable. We do, however, take great pains to minimize your pain.

We utilize a powerful topical anesthetic, a Tennant Biomodulator, a homey office environment, and our engaging personalities to make your visit as pleasant as possible.

Most people can drive home and resume unlimited activity following treatment. On rare occasions when oral sedation is employed, you must bring someone to drive you home.

Prolotherapy is not for everyone. It is only for those people who will do whatever it takes to get permanent relief from their pain.

Why is it so hard to find a doctor who gives this treatment? Prolotherapy currently is not 'mainstream' medical practice, although it is certainly moving in that direction. I am a Board Certified Surgeon, and a Fellow in the American College of Surgeons, so I would certainly not receive, nor give, a treatment that was not well founded and properly administered. If you ask physicians around the country what Prolotherapy is, you get responses like, 'alternative medicine, holistic medicine, natural medicine,' and, my personal favorite, 'never heard of it.'

In recent years, as advances in 'conventional medicine' have not provided the cures that patients desperately need, there has been a resurgence of interest in this useful and proven therapy. This treatment is over 70 years old, and has been published in reputable medical journals since the 1930's. The main problem at this time is that there is no formal training program where one can go to learn this procedure. There is only one way available to become a competent Prolotherapist. You must be mentored extensively by someone expert in the technique in order to become really proficient. That is why there are so few doctors doing it. There are weekend courses in Prolotherapy sponsored by two national organizations, and as people are beginning to seek out this therapy, some doctors are going to these courses, then going home and trying to 'learn on the job'. My advice to you: do not settle for less than the best.

Top 10 Reasons to Choose Prolotherapy Nashville
The Southeast's Premiere Prolotherapy Practice

WHAT'S IN A PROLOTHERAPY INJECTION?

Dr. Darrow Uses Safe Prolotherapy Injections To Stimulate Collagen Growth And Minimize Pain In this case to the HIP

PROLOTHERAPY INJECTIONS.... WHAT'S IN THEM?

As previously referenced (see "About Prolotherapy"), doctors use Prolotherapy injections with very mild solutions to stimulate the body's ability to generate collagen and minimize pain.

There are a number of different types of proliferation solutions which have proven to be successful that your Los Angeles, or Santa Monica Prolotherapy doctor can use. Although they work in different ways, each Prolotherapy injection motivates the body to heal itself through a variety of natural responses. However, the end result is the same: to cure pain by building new tissue and stabilizing the joints.

All of the solutions used in Prolotherapy injections are designed to have a "double-edged" effect: a combination of anesthetic and proliferant inflammatory qualities. The anesthetic agent alleviates the "pain trigger" while at the same time the proliferant agent begins to strengthen the ligaments and tendons at the tender points.

Some Prolotherapists use mild chemical irritants, such as phenol, guaiacol or tannic acid, to trigger the healing process. These substances attach themselves to the walls of the cells wherever they are injected, causing irritation that stimulates the body's reactive healing process. Others prefer to use chemotactic agents, primarily sodium morrhuate, a fatty acid derived from cod liver oil.

The dramatic sounding "osmotic shock agents" are actually simple compounds like dextrose and glycerine.These are the most commonly used ingredients in the arsenal of Prolotherapy. Extremely safe and water-soluble, they are easily excreted from the body after having their initial desired effect. They work by causing cells to lose water, which leads to inflammation and the subsequent stimulation of the healing

PROLOTHERAPY CAN HELP!

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response.

Particulates such as pumice flour are microscopic particles that attract macrophages, tiny organisms which gobble them up, in turn secreting polypetide growth factors that result in collagen production.

Besides these general differences, the specific combinations of chemicals and substances used are as varied as the “schools” of Prolotherapy using them.

Some practitioners add co-factors, such as the anti-oxidant mineral manganese, or a combination of glucosamine sulfate and condroitin sulfate which is believed to aid in the repair of arthritic joints, or other co-factors believed to increase the efficacy of the compounds they are used with.

Despite the enormous success of the compounds used today, the most exciting advances in Prolotherapy may be just around the corner, in the form of Growth Factors or Growth Hormones. In addition, fetal stem cells have been injected.

Growth factors act directly on the cells and joints of the body to stimulate the proliferation of fibroblasts and regeneration of collagen and cartilage.

The most important variable of all, however, as in all medical practices, is the ability and experience of the therapist one chooses. Besides being a licensed medical doctor, it is important that the Prolotherapist also be in tune with the underlying premise of homeopathy. It is not our duty to cure, but rather to entice the body into curing itself.

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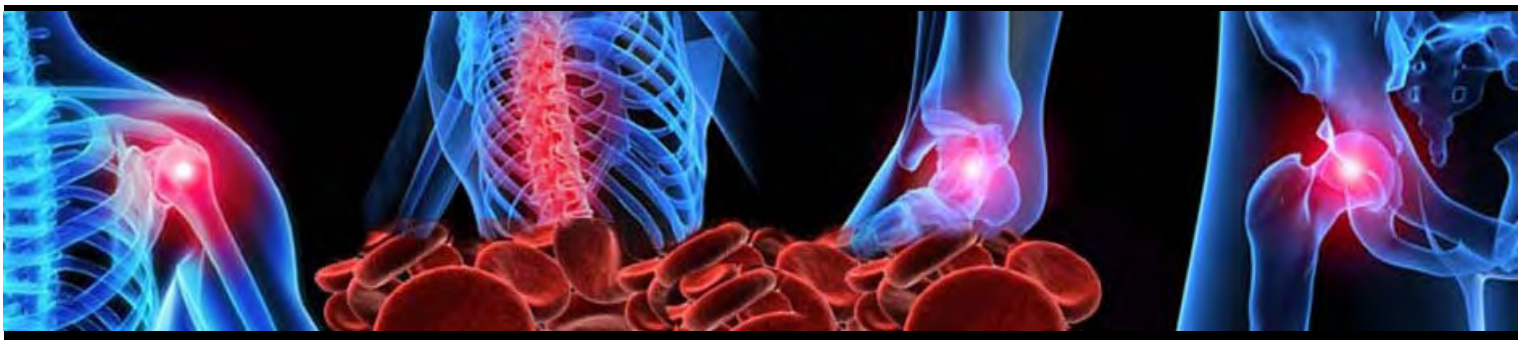

Retrospective Study Shows Prolotherapy is Effective in the Treatment of MRI-Documented Meniscal Tears and Degeneration

Posted on November 25, 2011 by admin

The Case for Utilizing Prolotherapy as First-Line Treatment for Meniscal Pathology: A Retrospective Study Shows Prolotherapy is Effective in the Treatment of MRI-Documented Meniscal Tears and Degeneration
Ross A. Hauser, MD, Hilary J. Phillips, and Havil S. Maddela

ABSTRACT
Meniscus injuries are a common cause of knee pain, accounting for one sixth of knee surgeries. Tears are the most common form of meniscal injuries, and have poor healing ability primarily because less than 25% of the menisci receive a direct blood supply. While surgical treatments have ranged from total to partial meniscectomy, meniscal repair and even meniscus transplantation, all have a high long-term failure rate with the recurrence of symptoms including pain, instability, locking (see loose bodies), and re-injury. The most serious of the longterm consequences is an acceleration of joint degeneration. This poor healing potential of meniscus tears and degeneration has led to the investigation of methods to stimulate biological meniscal repair.

Research has shown that damaged menisci lack the growth factors to heal. In vitro studies have found that growth factors, including platelet derived growth factor (PDGF), transforming growth factor (TGF), and others, augment menisci cell proliferation and collagen growth manifold. See The Regeneration of Articular Cartilage with Prolotherapy

Animal studies with these same growth factors have confirmed that meniscal tears and degeneration can be stimulated to repair with various growth factors or solutions that stimulate growth factor production. The injection technique whereby the proliferation of cells is stimulated via growth factor production is called Prolotherapy.

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Prolotherapy solution can include dextrose, human growth hormone (HGH), platelet rich plasma, and others, all of which stimulate connective tissue cells to proliferate. A retrospective study was done involving 24 patients, representing 28 knees, whose primary knee complaints were due to meniscal pathology documented by MRI. The average number of Prolotherapy visits was six and the patients were followed on average 18 months after their last Prolotherapy visit.

Prolotherapy caused a statistically significant decline in the patients' knee pain and stiffness. Starting and ending knee pain declined from 7.2 to 1.6, while stiffness went from 6.0 to 1.8. Prolotherapy caused large improvements in other clinically relevant areas such as range of motion, crepitation, exercise, and walking ability. Patients stated that the response to Prolotherapy met their expectations in 27 out of the 28 knees (96%)

Only one out of the 28 patients ended up getting surgery after Prolotherapy. Based on the results of this study, Prolotherapy appears to be an effective treatment for meniscal pathology. While this is only a pilot study, the results are so overwhelmingly positive that it warrants using Prolotherapy as first-line therapy for meniscal pathology including meniscal tears and degeneration.

Epidemiology of Meniscal Injuries
Knee injuries are a common concern resulting in over 1 million surgeries performed to the knee in the United States every year.1-3 According to the National Athletic Trainers' Association, knee injuries account for 10% to 19% of high school sports injuries and 60.3% of all high school athletic-related surgeries.4 Similar studies of collegiate sports have shown that knee injuries make up 7% to 54% of athletic injuries, varying by the nature of the sport.5-9 The leading injuries to the knee, in both adults and children alike, are primarily patellofemoral derangements or ligament strains and tears.10-12

Secondary to these injuries are meniscal tears, which have generated particular interest in both the young and elderly population as studies over the past several decades have revealed a rise in both degenerative and traumatic meniscal injuries. Meniscal tears occur as early as childhood, where they serve as the leading cause of pediatric arthroscopy, and increase with age and activity.13,14 An estimated one sixth of knee surgeries are performed for lesions of the meniscus, and it is likely that many more remain untreated every year.15,16 In one study of cadaver knees, untreated meniscal lesions were found in 34% of the autopsied subjects.17 A significant percentage of meniscal injuries result from athletic injury. On a professional level, meniscal tears accounted for 0.7% of all injuries sustained in the National Basketball Association, totaling 3,819 days missed by NBA athletes over a 10 year span.18

In college sports, studies conducted over a 16 year span by the National Collegiate Athletic Association Injury Surveillance System found internal knee derangement was second only to ankle sprains in both men's and women's college basketball and men's and women's soccer.5-8 An independent study of college football had equally devastating statistics, reporting injuries to the meniscus in roughly one in five elite college football athletes.9 With participation in college sports on the rise, the number of meniscal injuries and subsequent surgeries are consequently rising at an alarming rate.19 Although athletes appear to have the highest instance of injury, meniscus injuries can happen anywhere, regardless of a person's level of activity. A research study conducted in Greece showed that meniscal tears developed equally from traumatic and non-traumatic causes

with 72% of all meniscal tears occurring during normal activities of daily living.20

Anatomy and Function

The menisci (plural of meniscus) are a pair of C-shaped fibrocartilages which lie between the femur and tibia in each knee, extending peripherally along each medial and lateral aspect of the knee. (See Figure 1.) The anatomy of both menisci is essentially the same, with the only exception being that the medial meniscus is slightly more circular than its hemispherical lateral counterpart. Each meniscus has a flat underside to match the smooth top of the tibial surface, and a concave superior shape to provide congruency with the convex femoral condyle. Anterior and posterior horns from each meniscus then attach to the tibia to hold them in place. The meniscus is comprised of approximately 70% water and 30% organic matter. This organic matter is primarily a fibrous collagen matrix consisting of type I collagen, fibrochondrocytes, Proteoglycans, and a small amount of dry noncollagenous matter.21,27 There has been a great deal of speculation and research dedicated to what exact function the meniscus serves, but today there is general consensus that the menisci provide stability in the joint, nutrition and lubrication to articular cartilage, and shock absorption during movement.21-25 The menisci provide stability to the knee joint by both restricting motion and providing a contour surface for tibiofemoral bone tracking. The function of stability is shared with several ligaments which work together to prevent overextension of any motion. The transverse ligament connects the two menisci in the front of each knee and prevents them from being pushed outside of the joint at any point. Hypermobility is avoided through the connection of the medial collateral ligament (MCL) to the medial tibial condyle, femoral condyle, and medial meniscus, and the connection of the lateral collateral ligaments (LCL) to the lateral femoral epicondyle and the head of the fibula; these ligaments provide tension and limit motion during full flexion and extension, respectively. The anterior and posterior meniscofemoral ligaments form an attachment between the lateral meniscus and the femur and remain taut during complete flexion. Lastly, the anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) are responsible for preventing too much backward or forward motion of the tibia.23,24 The menisci also provide shock absorption and stability by equally distributing weight across the joint.

Sarasota, FL 34239

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Lakers' Bryant receives rare procedure on knee →

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PROLOTHERAPY AND TENDINOSIS

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PROLOTHERAPY AND TENDINOSIS
Ross Hauser, M.D.

Do you want to know the end result of a person treating their pain with rest, ice, bracing, immobility, anti-inflammatory medications and Steroid injections? Tendinosis, or at least some type of degeneration. It is amazing to me that very few people receive the diagnosis of tendinosis. Do you know why? It is because the body has tremendous regenerative capabilities. So while traditional medicine practices continue to inhibit the normal healing inflammatory reaction with ice, rest, anti-inflammatories, and cortisone shots, the body often still finds a way to rid itself of pain. But mark my words, if you continue to use anti-inflammatory medications, at some point your body will degenerate. Degeneration will occur because you are stopping the normal inflammatory reaction. It may not be tendinosis, but you will be left with a degenerated joint.

The final stage of tendon degeneration is called tendinosis. Tendinosis means tendon degeneration. We do not have such a term for ligament degeneration, but if you have been told you have chronic instability of a joint, most likely you have end stage ligament degeneration. Have you been told you have severe back, neck, shoulder, knee, hip, or ankle arthritis? Maybe you have been told you have “bone on bone” or you are close to getting it? If so then you have end stage joint degeneration. The mechanism by which all of these types of things occur is basically the same: traditional anti-inflammatory treatments.

Yes, anti-inflammatory medications and specific steroid or cortisone injections and its buddies, accelerate the degeneration of such structures as lligaments, tendons, and joints! The long term effect of these medications is tendon, ligament and joint degeneration. Tendon degeneration is called tendinosis. Some of the more common areas of tendinosis occur in the Achilles and elbow (extensor tendons). Under a microscope, tendinosis appears as lipoid or mucoid degeneration within the tendon with fibrinoid necrosis and discontinuity of tendon fibers. Microscopically, attempted healing is suggested by the presence of histiocytes and capillaries. Why again did the tendon not heal? Correct, because you kept icing the area, taking anti-inflammatory medications, and getting cortisone shots. The exercise you were doing during this time didn’t help like you thought it would.

What are you to do?
If you consult with an orthopedic surgeon, he/she will most likely recommend surgery. The tendinosis is removed and tendon is then sutured back to its origin or insertion site. With good rehabilitation there is a chance that in six to nine months you might be exercising again. Wow! That’s a long time to be side-lined, you think. Yes, it surely is! But is there a better way?

For over fifteen years, I have been treating people with tendinosis with Prolotherapy. Step one is to have them stop taking anti-inflammatories and to take supplements to aid in healing. I also do things to put their physiology in an anabolic state (growth). I do blood hormone testing and may get the person on some hormones such as human growth hormone, DHEA, or testosterone depending on the results. I may also use human growth hormone in the Prolotherapy solutions to aid in the repair of the degenerated tendon. Typically tendinosis is treated every two to three weeks for three to four visits. Often six visits are needed for the tendon to feel strong again and achieve full repair.

While a patient is undergoing Prolotherapy, he/she is still exercising, but the exercise must not be something that causes pain in the area. Movement is good for healing, as it increases blood flow to the area.

Prolotherapy is a great alternative treatment for tendinosis. However, I encourage you to first and foremost stop doing things that cause you to get tendinosis in the first place. If you have pain from a degenerative condition, taking NSAID’s or getting cortisone shots is a bad idea. Taking anti-inflammatory medications such as motrin or ibuprofen is a bad idea. Putting ice on an injury is a bad idea. All these treatments do is stop healing and increase the chances that your tendons, ligaments, and joints will become degenerated. The end stage of these conditions is called tendinosis (tendons), chronic instability (ligaments) and bone on bone phenomenon (joint).

I believe Prolotherapy is the best treatment for these conditions because it helps rebuild the degenerated tendons,

ligaments, and joints. Prolotherapy stimulates the body to repair painful areas such as tendons, ligaments, and joints. Prolotherapy stimulates the normal inflammatory healing reactions. Thus, a condition of tendinosis is temporarily changed to a tendonitis, with the long term goal being a normal strengthened tendon. A person with the diagnosis of tendinosis should expect to get at least six sessions of Prolotherapy. As discussed above healing is maximized by proper diet, supplements, and gentle exercise. So if you have been told that you have tendinosis or degenerative arthritis, first stop doing things that accelerate the process, then take a trip to Oak Park, Illinois to your local Prolotherapy doctor.

Visit Benuts Nutritional Supplements for any of the nutritional products listed in the article above.

Platelet Rich Plasma, Stem Cells, and Other Growth Factors

The healing effect of Prolotherapy is a graded, controlled reaction producing repair of the weak and damaged connective tissue with new healthy collagen. When properly applied, Prolotherapy does not induce scar formation. The bonds are stronger, healthier, and thicker than before treatment, and with each treatment continue to strengthen, until the healing is complete and the pain resolved. There are new, advanced versions of Prolotherapy which may in time prove to have specific effects that exceed the effects of standard Prolotherapy solutions. Since standard Prolotherapy solutions have been proven for over 75 years with millions of successful patient treatments, advanced solutions are not necessary for most conditions. However, moderate to severe tears of tendon, ligament, or cartilage within a joint may potentially require a stronger agent to achieve an optimal outcome. Examples of these include the following:

Human Growth Hormone (HGH) has been successfully injected into joints to induce growth of cartilage. HGH increases cartilage thickness and repair. The use of HGH is somewhat controversial however, due to the inappropriate systemic use of HGH in the professional athlete population to increase muscle mass and performance.

Platelet-Rich Plasma (PRP) is derived from the patient's own blood and is placed in a centrifuge, to obtain a concentrated fluid rich in platelets and growth factors. This is then injected into the tendons and ligaments to stimulate growth and repair. A recent article in many nationwide newspapers including the New York Times (PRP New York Times) discusses this procedure and its outcome in professional athletes.

Mesenchymal Stem Cells (MSC's) are derived from the patient's own fat tissue and bone marrow. Techniques are being studied to take advantage of the powerful repair that stem cells can produce. The use of the patient's own tissues eliminates the issues of allergic reaction, genetic tissue interchange, rejection of tissue transplantation, and unintended or unknown infectious agents that would be a potential risk using tissue derived from another person. The ethical consequences of using embryonic fetal cell tissues are also completely avoided. We are currently using stem cells harvested from both bone marrow and adipose tissue, combined with Platelet-Rich Plasma, injected within and around the joint to produce a potentially more powerful strategy for growth and repair of complex injuries.

Prolotherapy with newer growth-stimulating factors appears to have similar safety to date as standard Prolotherapy. The theoretical risks are similar but have proven to be quite rare: infection, nerve injury, bruising, air in the lung (pneumothorax) during a rib cage procedure, etc. Careful adherence to injection site sterility and precise needle technique generally appears to virtually eliminate these risks.

Since Prolotherapy with standard solutions routinely greatly benefits more than 80% of patients, advanced solutions are used mostly in more challenging situations, such as substantial cartilage loss, complex meniscus tears, labral tears, and deep osteochondral defects. The evidence suggests that we are entering a new realm of Prolotherapy in which additional factors will be discovered that improve upon the excellent results and low risk of Prolotherapy.

David P. Nebbeling, D.O.

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Non-Surgical Joint Reconstruction

Prolotherapy / Schlerotherapy

What is Reconstructive Therapy?

Non-Surgical Joint Reconstructive Therapy is an injection technique similar to "prolotherapy" or "sclerotherapy." These therapies promote the re-growth of the cells and tissue that stabilize and strengthen weakened joints, cartilage, ligaments, and tendons. Reconstructive Therapy can be used wherever ligaments, tendons, cartilage, and / or discs are torn and worn. Non-Surgical Joint Reconstructive Therapy is different from prolotherapy and sclerotherapy only because it is a comprehensive treatment program that includes: 1) an injection technique, 2) nutritional programs designed to aide the body in tissue re-growth, and 3) an over-all detoxification program.

Hips before Reconstruction

Hips after Reconstruction

What problems can Reconstructive Therapy address?

Non-Surgical Joint Reconstruction can repair nearly any torn and worn ligaments in the body. This is how it works: Your ligaments function as the primary stabilizers of the joints in your body. They connect your bones to each other. Ligaments also function to limit the range of motion that your bones can move between each other. Tendons connect your muscles to your bones in order to provide motion.

The Spine

Your spine, for example, is composed of bone, tendons, ligaments, discs, and cartilage. Discs and cartilage serve as shock absorbers and keep your bones from rubbing against one another. In acute injuries, the ligaments and tendons become torn and are unable to stabilize joint areas. This causes the discs or cartilage to become worn down. They may also be worn down by repeated

motion. This wear-down ultimately leads to joint instability resulting in constant pain, less mobility, and lack of endurance. Reconstructive Therapy can return such a joint to a healthy state.

Ligaments and Sprains

Even ligaments can be re-grown with Non-Surgical Joint Reconstruction. Ligaments are connective tissue made-up of collagen. When ligaments are torn, it is called a sprain. Ligaments may also become over-stretched or lax due to chronic over-use. Torn ligaments can lead to joint instability and osteoarthritis. Reconstructive Therapy can stop this process. First, a small amount of sclerosing solution is injected on the ligament. This solution causes controlled inflammation, which leads to the release of fibroblastic growth factor or FGF. FGF will stimulate fibroblasts to lay down collagen. This process can completely re-grow damaged ligaments. Each treatment results in more and more tissue being laid down in the needed areas. As a result, the joints continue to become stronger and more stabilized and the natural functions of the body are regained.

Torn Rotary Cuff

In the case of a torn rotary cuff, the four tendons that come together to form the rotary cuff become frayed. Patients who have torn rotary cuff will report pain in the shoulder region when attempting to raise their arm into certain positions. With Reconstructive Therapy, a small amount of sclerosing solution is placed at the attachment point for the tendons of the rotary cuff and along the edges of the bones, causing controlled inflammation at the shoulder joint where the ligaments attach. The sclerosing solution stimulates the body to re-grow these tissues. Over a few weeks of treatment, the pain will lessen and strength and range of motion will increase and return.

Cartilage Replacement

When a knee or other joint is "bone on bone," Non-Surgical Joint Reconstruction can help by rebuilding the cartilage. In knee cartilage replacement surgery, for example, doctors take chondrocytes -- the cells that grow cartilage -- and bathe them in a solution containing FGF. FGF stimulates chondrocytes to grow cartilage and the cartilage is surgically implanted into the area in an existing piece of knee cartilage. With Reconstructive Therapy, however, the injections stimulate your body to release FGF at the joint site, re-growing particular cartilage at the ends of the bones **without surgery!** In the advanced therapy program, Human Growth Hormone (HGH) is injected inside a knee, hip, or shoulder joint to stimulate re-growth of large pieces of cartilage.

With Non-Surgical Joint Reconstruction methods, pain will become less and less until, in almost all cases, it entirely disappears. Your body will heal and regain normal function without drugs or surgery!

What other problems can Reconstructive Therapy address?

- Osteoarthritis / rheumatoid arthritis
- Pain after joint surgery
- Carpal tunnel / tennis elbow / whiplash / T.M.J.
- Pain after an accident

Remember, Non-Surgical Joint Reconstruction promotes the body's own natural healing abilities. There is no down time, no real side effects and can often even be used when surgery fails. With Reconstructive Therapy, results are **permanent.**

10 Vital Poinits to Know about Non-Surgical Joint Reconstructive Therapy

- Promotes the body's own nautral healing ability.
- The natural functions of the body are regained and optimized.
- No drugs or surgery are used.
- Relieves pain and increased motion and function.
- In a double blind human study, where neither the patients nor the researchers knew specifically who was recieving the treatment, 88.4% of those injected with the reconstructive solution showed improvement.
- Capable of increasing the strength and structure in ligaments and tendons from 30% - 40% over the norm.
- Results are permanent. Can improve or resolve so-called "incurable cases".
- No down time. Is both diagnostic and therapeutic.

- No significant side effects.
- Very conservative treatment. Can be used as an alternative to surgery or when surgery fails.

Neural Therapy

Often times Neural Therapy is used in conjunction with Reconstructive Therapy. Neural Therapy is an injection technique known to provide instant relief of pain, increased motion, and return of function for problems that are untreatable by other methods.

How does Neural Therapy repair nerves?

Neural means "of the nerves." Nerves work by having a normal nerve flow, which monitors and controls all the body's parts. Muscles move because of nerve flow to them. The heart beats because of nerve flow controlling it. All of the special senses and internal organs work due to the control of the nerves. This nerve flow is critical to the sensation, function, and movements of the entire body.

When nerves become damaged through surgery, injury, falls, burns, and so forth, this vital nerve flow is broken. The broken nerve flow is like a short circuit in your house wiring. Pain, lack of motion, loss of function, poor endurance, and many other body control malfunctions result from the broken nerve flow and remain until the nerve flow is restored.

Everyone knows that local anesthetics block pain. The new information is that local anesthetics can restore normal nerve flow. When the nerve flow is restored, the function and energy are instantly corrected. The pain and other sensory problems also instantly improve or resolve.

The nerve flow is restored by the exact placement of local anesthetic into and around the precise nerves involved. The injections are done with a very thin needle.

For further information about Non-Surgical Joint Reconstructive Therapy, references, and over 100 case histories, read Dr. Faber's books *Pain, Pain Go Away* and *Instant Pain Relief*. You can also go to www.milwaukeepainclinic.com for more information and case histories.

Don't learn to live with pain and disability. Heal your body naturally without drugs and surgery with proven methods that get results.

Contact Us! about Non-Surgical Joint Reconstruction today!

David P. Nebbeling D.O.
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Lansing, MI 48917-4214

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info@davidnebbelingdo.com

Standard Clinical X-ray Studies Document Cartilage Regeneration in Five Degenerated Knees After Prolotherapy

ROSS A. HAUSER, MD & JOSEPH J. CUKLA, LPN

From the *Journal of Prolotherapy*. 2009;1:22-28.

Abstract

Degenerative joint disease is the most common form of arthritis. The condition is marked by progressive destruction of the articular cartilage which is easily documented by standard X-ray studies. The regeneration of this articular cartilage in clinical practice has been difficult. Five knees with articular cartilage degeneration were treated with Prolotherapy in this report. Each of the five knees showed improvement of their standard clinical X-rays after the Prolotherapy, signifying articular cartilage repair with Prolotherapy. It is suggested that before and after X-ray studies can be used to document the response of degenerated joints to Prolotherapy.

Introduction

Osteoarthritis (OA) is one of the major problems affecting our aging population. It has been estimated that two to three percent of the adult American population suffers from regular pain from Osteoarthritis OA, and approximately one-third of adults in the US between the ages of 25-74 have radiological evidence of OA in at least one of the major joints.[1] Autopsy specimens have demonstrated a 90% prevalence of articular cartilage degenerative changes in weight bearing joints in individuals older than 40 years old.[2] The knee is the most symptomatic joint affecting 6.1% of all adults over the age of 30 but rising to 16% of adults over the age of 45.[3-5] Because there is no currently accepted method to stop or reverse joint degeneration, the incidence of symptomatic OA increases by about 1% each year.[6]

Osteoarthritis is the most common form of knee arthritis and can involve any or all three compartments in the knee: the medial compartment (medial tibial plateau and medial femoral condyle); the lateral compartment (lateral tibial plateau and lateral femoral condyle); or the patellofemoral compartment (patella and femoral trochlear notch).

The increasing number of joint complaints and radiological OA is matched by the rising

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number of major joint replacements. In one state alone the total number of total knee replacements increased by 81.5% from 1990 to 2000, with a subsequent rise in costs for these procedures of over 200%.[7] It is estimated that in the US, the total number of joint replacement surgeries of the hip and knee will increase from 684,000 cases in 2003 to over a million by 2013.[8]

The current conservative treatments for OA including medications, exercise, physical therapy, corticosteroid injections, weight control, Synvisc and Hyalgan injections, and operative treatments including arthroscopy often leave people with residual pain.[9-12] Because of this, many people with OA are seeking alternative treatments including Prolotherapy.[13-14]

Prolotherapy, also known as regenerative injection therapy, involves the injection of substances into degenerated or injured areas to stimulate healing.[15-17] While it has been traditionally used for ligament and tendon injuries, it has a long history of use in OA.[18-20] Two placebo-controlled double-blind studies by K. Dean Reeves and associates have demonstrated beneficial effects of Prolotherapy on OA including some X-ray changes.[21-22]

This report documents the results in five degenerated knees treated with Prolotherapy. Before and after X-rays were available to document articular cartilage regeneration with Prolotherapy.

Methods

Three patients representing five degenerated knees underwent Prolotherapy at the private practice of the primary author at Caring Medical and Rehabilitation Services in Oak Park, Illinois. Each patient underwent standard Hackett-Hemwall Prolotherapy to the knee.[23] Each patient had the following areas injected: intraarticular, pes anserine, medial collateral and lateral collateral ligament attachments, and medial side of the patella. The basic solution used was 15% dextrose and 10% Sarapin. Each joint received 2IU of Human Growth Hormone by injection. A total of 5 to 10cc of Prolotherapy solution was injected into the joint at each visit. Four hundred milligrams of glucosamine sulfate was added to one of the 10cc syringes. A total of 30 to 40cc of Prolotherapy solution was used per knee at each visit. This represented 20 to 30 injections per knee per visit.

Case Descriptions

Case One: CW is a 72 year-old woman who presented in July 2004, complaining of a five-year history of severe right knee pain. She rated her knee pain on the visual analogue scale (VAS) at a level of 6 on a scale of 0 to 10. She experienced daily pain throughout the whole knee and noted that the severity of the pain was also increasing. Her other symptoms were increased pain upon sitting for long periods of time, difficulty with stairs, and increased pain with walking. She was not exercising. She had no previous history of trauma or knee surgery. Three previous hyaluronic acid treatments provided diminishing relief. She used the oral pain relievers, tramadol hydrochloride and acetaminophen, as needed. X-rays done in 2002 showed osteoarthritis, marked loss of joint space medially, subchondral sclerosis and osteophyte formation. CW was told by an orthopedist that she needed a total knee replacement. She read about Prolotherapy in an alternative medicine newsletter and wanted to try it instead of surgery.

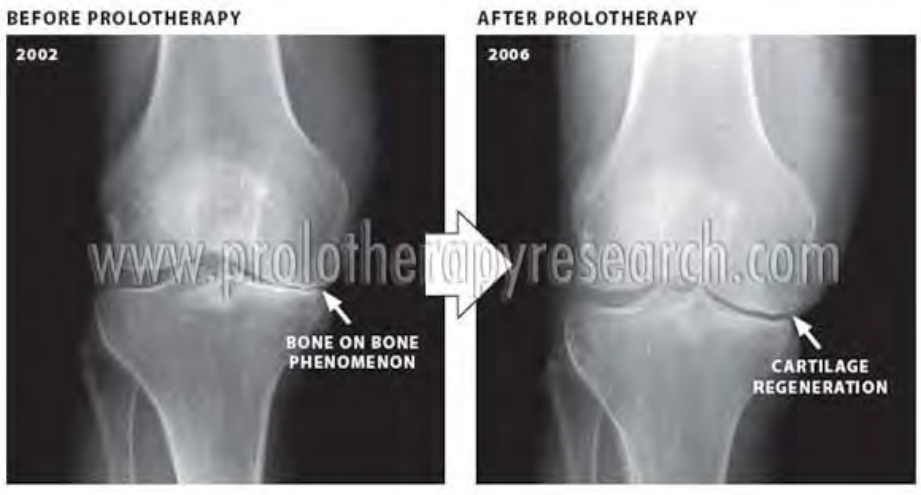
Physical examination showed normal knee alignment. Lachman, anterior drawer, valgus and varus stress tests were all negative. She exhibited joint line tenderness both medially and laterally, but worse medially, as well as quite a bit of crepitus in the knee throughout the range of motion. There was no swelling present in the knee. Her range of motion was 3 to 95 degrees.

Prolotherapy treatments began in July 2004. CW received nine treatments on her right knee through May 2005. She reported an incremental decrease in pain and increased mobility as she was interviewed every four to six weeks during the course of treatment. Her range of motion had improved to full extension and flexion to 110 degrees. Her crepitus was nearly nonexistent. She reported at this time, "I am 97% better. I have no pain (VAS score 0), just mild stiffness that subsides with walking." She was treated one more time and told to return to the clinic if the pain returned. She no longer needed medications or a total knee replacement.

CW returned to the clinic in May 2006 because she twisted her knee and some of her pain returned. Her physical exam at that time was unchanged from when she was seen in May 2005, except she showed more medial joint line tenderness and tenderness at the pes anserine area. She received four more treatments over the next four months, making incremental improvements in her pain. At this time, the patient was doing great, yet desired to see "how my cartilage was doing." The X-rays showed a large increase of medial joint space. (*See Figure 1.*) By this time, the patient had received 14 Prolotherapy treatments to her knee.

Seventeen months after her last Prolotherapy doctor treatment, the patient continues to have full function of the knee with almost no pain (0 to 1 on VAS). She has returned to full activities without pain and is on no pain medications.

Figure 1. Standard weight bearing knee X-rays of C.W. before and after Prolotherapy. The widening of the medial joint space width indicates that cartilage regeneration has taken place.



Go to the Journal of Prolotherapy to read Case Two: Three year history of bilateral knee pain.

Dr. Purita in New York Times

Pitcher's Treatment Draws Scrutiny

The Yankees signed Colon in January after he pitched during the off-season in the Dominican Republic. His fastball — often registering at 93 miles per hour or better — appeared to be back. The 37-year-old Colon has gone 2-1, with an earned run average of 3.81, since being inserted into the club's starting rotation.

A doctor in Florida would like to take some of the credit. Joseph R. Purita, an orthopedic surgeon who runs a regenerative medicine clinic in Boca Raton, said he and a team of Dominican doctors that he led treated Colon in April 2010. Purita said he employed what he regards as one of his more pioneering techniques: he used fat and bone marrow stem cells from Colon, injecting them back into Colon's elbow and shoulder to help repair ligament damage and a torn rotator cuff.

Dr. Joseph R. Purita

Purita said he flew to the Dominican Republic and performed the procedures for free, doing it at the behest of a medical technology company based in Massachusetts that he has done business with for several years. Purita, who has used human growth hormone in such treatments, said in an interview that that he had not done so in Colon's case. The use of human growth hormone is banned by baseball.

"This is not hocus-pocus," Purita said in an interview here. "This is the future of sports medicine, in particular. Here it is that I got a guy back playing baseball and throwing pitches at 95 miles an hour."

Purita said that he has treated at least two dozen professional athletes over the years, mostly baseball and football players, and that he has never given any of them H.G.H.

"I just won't give it to these guys," Purita said. "I don't need the stigma and that kind of reputation."

For the last few years, baseball and other sports, while fighting to limit the use of performance-enhancing drugs, have been faced with a new and murky challenge: players getting sophisticated blood treatments, often from doctors whose practices involve the regular use of H.G.H.

Brian Cashman, the Yankees' general manager, said Wednesday that he had not known of Colon's medical treatment when the club signed him. Cashman said Colon's agent, aware that The New York Times was working on an article about the procedure and Purita's role, had notified him recently of the procedure.

Cashman said he had, in response, informed Major League Baseball.

"The Yankees did notify us and we are looking into it," said Pat Courtney, a spokesman for Major League Baseball.

In October, a federal grand jury in Buffalo indicted Anthony Galea, a Canadian doctor, on charges that he provided many of the professional athletes he treated between July 2007 and September 2009 with human growth hormone and unapproved drugs. Galea was unlicensed to practice in the United States and yet had developed a reputation for helping athletes recover from injuries by using a blood-spinning technique known as platelet-rich plasma therapy. The athletes he treated included Alex Rodriguez, Tiger Woods, Jose Reyes, Carlos Beltran and the Olympic swimmer Dara Torres.

Those athletes have denied receiving H.G.H. Galea has acknowledged using H.G.H. himself but has denied providing any performance-enhancing drugs to professional athletes.

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Purita said he has treated athletes with the Baltimore Ravens, the Miami Dolphins, the Chicago White Sox and the Texas Rangers in recent years.

About 14 months ago, Purita said, Harvest Technologies Corp., a Massachusetts company that has done work in the adult stem cell field, contacted him. Purita said the company told him that a doctor in the Dominican Republic, Leonel Liriano, was looking to get Colon treated.

Colon, who has twice won 20 games in a season in his career, had struggled with injuries after winning the 2005 American League Cy Young award. In the next four seasons, he made only 48 appearances with three different teams. An elbow injury sidelined him for the final two months of the 2009 season, and he did not play at all in the majors in 2010.

Purita said he agreed to go to the Dominican Republic to work with Liriano and treat Colon.

“It was not that it was illegal to do the procedure here in the United States,” Purita said. “He was just living in the Dominican Republic. Everything was above board.

“Colon said he wanted to get back into baseball,” Purita recalled. “He could not throw the ball without horrible pain, but he felt he still had something left in the can, so to speak. I told Colon this will be a lot less painful than facing Derek Jeter. He said: ‘Derek Jeter? He has never been a problem for me. I always strike him out.’ ”

Liriano, a physician at Clinica Union Medica in the city of Santiago, where the procedure was done, said a cardiologist, a general surgeon, an anesthesiologist and an orthopedic surgeon were also present for the treatment.

“He showed us how to do the procedure,” Liriano said of Purita. “This was the highest-profile athlete I had worked on. I had done some Dominican basketball players before that.”

Some experts in the field were cautious in assessing the efficacy of such stem cell treatment.

Dr. Freddie H. Fu, chairman of the department of orthopedic surgery at the University of Pittsburgh School of Medicine and the University of Pittsburgh Medical Center, said, “Bone marrow is a good source of stem cells, but I don’t think there is any definitive evidence to show that it will benefit a condition like this.”

Fu added: “You need more of a scientific study. Just the use of this generally should not be done because it is not shown to be effective. In this case, we don’t know how the body’s natural healing abilities, along with the player’s own training, influenced the outcome. We know how stem cells work in cancer and AIDS patients. But in sports, we just don’t know. There is a lot of hype.”

Purita said that once the procedure was done — it lasted roughly 45 minutes, he said — the results were evident.

“We had him start working out within the first month,” Purita said. “Then I am hearing that he is starting to pitch, and then I hear that he is starting to tear them up in the Dominican league. But I said with a rotator cuff tear and a bad elbow, I don’t know about him getting back into the majors.”

Colon was pitching for a Dominican winter ball team managed by Tony Pena, the longtime Yankee coach. Eventually, the Yankees signed him to a contract for $900,000, a relative bargain.

Once the season started, Colon’s role grew in importance. He has taken Phil Hughes’s spot in the rotation, and been a considerable surprise. He is scheduled to start Friday night’s game against the Red Sox at Yankee Stadium.

Colon, whose English is limited, answered only, “I don’t know, I don’t know,” in Spanish when asked last week about his medical treatment in the Dominican Republic. He was not available in the team’s clubhouse Wednesday evening.

“I feel in my heart and my soul, his performance has been because of the treatment,” Liriano said. “You see that his fastball is about 95 or 96 miles per hour. It is a miracle, no?”

Purita, for his part, is proud, but less conclusive.

“This is not just about what we did,” he said. “We gave him the means, but he has the focus and desire, the killer instinct. He worked his tail off to get back in the game. That is something stem cells cannot fix.”

Colon’s agent, Mitch Frankel, agreed. “The doctor feels that it definitely gave him a jump start to his improvement, although for me, personally, I don’t think Bartolo was focused on baseball mentally or physically for the last few years,” Frankel said. “I believe the problem was that and not his pitching. And I think once he made that determination, you can see the success.”

Still, Liriano said he was hopeful he could persuade the retired Pedro Martinez to undergo the treatment and consider a return.

“I have not gotten any response yet,” Liriano said. “We are focusing on high-profile athletes whose best years are gone.”

Ben Shpigel, Katie Thomas, Toby Lyles and Alain Delaqueriere contributed reporting from the New York Times.

GHRP2
Growth Hormone Release Peptide-2

Human Growth Hormone

Human Growth Hormone (HGH) Replacement Therapy

It has been shown that as we age, our bodies' natural GH production decreases. Many of the effects of aging are seen as a result of this decrease. More important, clinical evidence and recent medical research clearly demonstrate that by replacing Human Growth Hormone in IGF-1 deficient adults, we can significantly eliminate these symptoms, reverse the biological effects of aging, reduce body fat, increase lean muscle mass, strengthen the heart and improve sexual performance. No other substance known to medical science has been shown continually to deter and reverse the process of aging.

In many cases, you can reasonably look to reverse ten to twenty years of age decline with one year of continual therapy.

Injectible Human Growth Hormone Available! Inquire for pricing

What is HGH?

Human Growth Hormone is an endocrine Hormone that is produced by the anterior portion of the pituitary gland. It is made up of 191 amino acids. Production of GH decreases as we age. Virtually every system in the human body is in some way dependent on HGH for proper functioning. Growth Hormone peaks during adolescence and decreases dramatically thereafter. At age 40, our GH production is only 40% of what it was at age 20. Levels are measured by IGF-1.

Benefits:

Abdominal Fat Reduction

Growth hormone promotes the action of insulin. When we use GH/ IGF-1 Precursor, it directs the action of insulin towards putting sugar into the cardiac, muscle and nerve cells, rather then into fat cells. By getting rid of abdominal fat, you can induce greater insulin sensitivity. Greater insulin sensitivity can help prevent, and in some cases reverse type 2 adult onset diabetes.

Increase Lean Muscle

There is an average increase of 9% in lean muscle mass in use of HGH for one year, as well as

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Phone *Required | Email *Required

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City | State (Select State)

Zip | Age

Height (ft / in) | Weight (lb)

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Health Concerns / Health Goals

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reduction of 14% in body fat in just six months of HGH use.

Sex Drive

The decline of the male and female libido is directly related to the age-related declines in Hgh and Testosterone in the body. A clinical study of 302 aging adults showed that HGH and/or Testosterone Replacement Therapy improved sexual potency and frequency in 75% of the men studied. Interviews with people on Hgh Replacement Therapy indicate that almost everyone, men and women, had improvement in sexual function.

Fewer Wrinkles

Growth hormone helps with the promotion of type-2 collagen which adds elasticity to the skin.

Healing Joints

GH also has an anabolic effect on soft tissue such as tendons, cartilage, and other connective tissue. This signifies that old injuries can repair at an accelerated rate and with more strength due to stronger connective tissue.

Metabolic Cascade

When we age without Rejuvenation, the efficiency of our overall endocrine system i.e., thyroid, pancreas, adrenal cortal, hypothalmic pituitary axis (HPA), etc. becomes tired and worn down.

In addition to this problem, a degenerative metabolic cascade takes place within yourself as less and less hormone/messengers are produced. The receptor sites also start to lag and some become switched off -- and as in menopause some disappear altogether. Thus the receptor sites target areas for some hormones messengers which are no longer there.
This problem demonstrates why some improperly administered HRT therapies are not effective.

GH has a very potent anabolic effect (protein synthesis/tissue building) which can cause an increase in the number of cells and the enlargement of muscle cells. The goal of restoring, retuning and maintaining youthful hormone levels helps to jumpstart tired worn receptors. Since GH/IGF-1 precursors rejuvenate on a cellular level/cell division, the overall effect of systemic endocrine rejuvenation has a long lasting list of benefits.

Thus it is essential that doctor administered protocols, with the help of doctors assistants for monitoring therapies are followed properly. Proper and timely Dosage Administration along with guidance in nutrition, adds a synergy with gratifying, satisfying results.

GH itself is not responsible for the majority of the effects seen from GH use. Actually it is only the precursor to the so called Good Stuff IGF-1.

Dr. Purita in New York Times

Pitcher's Treatment Draws Scrutiny

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EXHIBIT C

CYTOKINE AND CHEMOKINE RELEASE FROM PLATELET-RICH PLASMA

A. **Objective**: To correlate the clinical efficacy of platelet-rich plasma (PRP) in the treatment of patellar tendonosis, lateral epicondylitis, and muscle tears with cytokine and chemokine levels. The latter include but are not limited to platelet derived growth factors, SDF-1alpha, and matrix metalloproteinases (MMP).

B. **Background**: Tendon and ligament injuries require prolonged convalescence and healing is often suboptimal. Numerous animal models have demonstrated the positive effects of growth factors, enhancing cellular migration and proliferation, angiogenesis, and matrix deposition in tendon and wound healing.[1-3]

Collagen synthesis is essential for tendon and ligament regeneration. Following injury COL3A1 synthesis is increased forming irregular interfibrillar crosslinks to contribute early stability while COL3A1 gradually increases to restore the normal tendon architecture. It has been reported that the MMP mediated degradation of tendon results in increased production of COL3A1.

Degenerative lesions typical of tendonopathy may reflect MMP-mediated matrix degradation. The role of catabolic stimulation in regeneration of acute or chronic injuries is unclear. Several studies have demonstrated MMP-3 to be decreased which may reflect a failure of physiologic remodeling.[4]

The role of MMP-13 in tendon degeneration is firmly established, MMP-13 degrades the fibrillar collagen types I, II, and III. There are also substantial increases in MMP-13 in both acute and chronic tendonopathy and tendon rupture[5]. A soon to be published study has demonstrated that PRP does not upregulate MMP-13 expression.[6]

It is important to define the rationale for the treatment of injuries such as tendonosis and muscle tears with PRP. Based upon the demonstrated cytokine

and chemokine release, it is far beyond PROLOTHERAPY. The proposed study will correlate platelet releasate with clinical outcome.

C. **<u>Methods</u>**: For most of your procedures 7 mL of PRP will be required. To complete the studies detailed below will require the processing of 120 mL of whole blood yielding <u>+</u> 14 mL of PRP. Samples for ELISA testing (cytokine-chemokine) will be stored at -80°C. They will be tested in groups of 40. The CBC results will be faxed to you on a daily basis. These will be forwarded by the testing laboratory.

Study samples can be obtained Monday through Thursday. The laboratory is closed on the weekend. We will let you know well in advance if there will be days that are not good for us – i.e. travel or meetings, even vacation.

1. **Blood Collection**:
    a) Perform phlebotomy following manufactures instructions
    b) Draw 9 ml whole blood into one 10 ml syringe containing one ml ACD-A anticoagulant. Attaché a sterile tip cap. Invert several times.
    c) Draw 54 ml whole blood into each of two 60 ml syringes each containing 6 ml ACD-A anticoagulant. (total 120 ml) for processing in the Harvest Smart PReP system.
    d) Place the 10 ml whole blood sample into a labeled sterile 14 ml Falcon tube.
    e) Following processing of the two 60 ml whole blood samples, remove PPP from each PD leaving 7 ml in each of the PD's. Place PPP into a labeled sterile 50 ml Falcon Tube.
    f) Using a single 20 ml Syringe with blunt cannula, re-suspend PRP and withdraw PRP from both PD's into the single PRP syringe. Total volume should be 14 ml.

g) Transfer 7 ml of the recovered PRP to a treatment syringe and place the remaining 7 ml of PRP into a labeled 14 ml Falcon Tube.

h) Follow packaging instructions for patient samples and ship samples same day overnight to testing laboratory.

2. **Analysis of baseline samples**

a) CBC – automated

b) Plasma

SDF-1α

TGF-B1, and PDGF-AB, VEGF

MMP-9

MMP-3

MMP-13

c) Whole blood – thrombin activated

SDF-1α

TGF-B1 and PDGF-AB, VEGF

MMP-9

MMP-3

MMP-13

3. **Analysis of PRP product.**

Even though the product from each donor is consistent it is our suggestion that the two 7 mL samples be pooled. We would need 7 mL and will supply test tubes.

a) CBC – automated

b) PRP product activated with thrombin

SDF-1α

TGF-B1, and PDGF-AB, VEGF

MMP-9

MMP-3

MMP-13

c) Plasma removed from PRP prior to activation.

SDF-1α

TGF-B1, and PDGF-AB, VEGF

MMP-9

MMP-3

MMP-13

Clinical evaluation and studies required:

Pre and Post 3 dimensional ultrasound using a pressure gauge to apply clinical pressure scores on the site of pain.

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2. Dowling, BA, et al: Equine Vet J 2000; 32:364.
3. Wearing, SC, et al: Sports Med 2006; 36:585.
4. Tsuzaki, M, et al: J Orth Res 2003; 21:256.
5. Lo, IK, et al: Am J Sports Med 2004; 32:1223.
6. McCarrel, T, et al: J Orth Res; 2009

Addendum:

Shipping container – Fedex to testing laboratory containing:

a) 1x 15 ml Falcon sterile tube – WB
b) 1x 15 ml Falcon sterile tube – PRP
c) 1x 50 ml Falcon sterile tube – PPP
d) Data sheet
e) Patient history

EXHIBIT D

North America Platelet-Rich Plasma Symposium

September 9, 2011
Renaissance Toronto Downtown Hotel
Toronto, ON, Canada

Join us for a day of learning on the growing use of platelet-rich plasma in orthopaedic applications. Recognized experts will review the uses and applications of PRP through lectures, discussions and live demonstrations.

Course Faculty

- Moderator - Anthony Galea, MD
  Institute of Sports Medicine and Wellness, Etobicoke, ON
- Sherwin Kevy, MD
  Immune Disease Institute, Harvard University, Boston, MA
- Gordon Ko, MD
  Sunnybrook Health Sciences Centre, Markham, Ontario
- Ken Mautner, MD
  Emory Healthcare, Atlanta, GA
- Joseph Purita, MD
  Boca Raton Orthopedic Group, Boca Raton, FL
- Steve Sampson, DO
  The Orthohealing Center, Los Angeles, CA
- Michael Scarpone, DO
  Riverside Medical, Steubenville, OH
- Henry Stiene, MD
  Beacon Orthopaedics & Sports Medicine, Cincinnati, OH

Topics Include

- Defining the Composition and Healing Effect of Platelet-Rich Plasma
- Lower & Upper Extremity applications
- Case Studies & Protocols
- Live Demonstrations
- The Future of PRP

Course Location

Renaissance Toronto Downtown Hotel
1 Blue Jays Way
Toronto, ON M5V 1J4, Canada
Sept. 9, 2011 - 9 am - 5pm
Lectures 9 am - 4 pm
Live Demonstrations 4 - 5 pm
Lunch & refreshments will be provided

Course Fee

- $495

Enrollment in this Symposium is Limited

For more information email kjames@harvesttech.com

Course Registration

Name:	☐Check/Money Order ☐ Visa ☐Mastercard ☐Amex Make check payable to Harvest Technologies Corp.
Organization:	Card Number: Exp. Date:
Address 1:	
Address 2:	Names as it appears on card
City, St, Zip:	
Phone:	Authorized Signature:
Fax:	
Email:	*Cancellation 7 days or less before no refund

Fax or Mail Completed Form to:
Harvest Technologies Corp. Attn: Kim James
40 Grissom Rd. Ste.100, Plymouth, MA 02360
(F) 508-732-0400 (P) 508-732-7534

Hotel Reservations:
Renaissance Toronto Downtown Hotel ($239/nt)
1 Blue Jays Way
Toronto, ON M5V 1J4, Canada - (416) 341-7100

Harvest Technologies, Mass.-based company, draws criticism for choosing moderator Dr. Anthony Galea

BY CHRISTIAN RED
DAILY NEWS SPORTS WRITER
Sunday, June 05, 2011

Imagine a major financial investment firm holding a symposium and inviting Bernie Madoff to be the keynote speaker.

An analogous situation could be drawn with Harvest Technologies.

The Massachusetts-based company that manufactures equipment for platelet-rich plasma (PRP) therapy procedures - a legal and increasingly popular form of treatment that has sky-rocketed within sports medicine in the last few years - is sponsoring a PRP symposium in Toronto in September. But the company is already drawing criticism in both the medical profession and anti-doping circles for its choice to moderate the event: Toronto physician Anthony Galea.

Galea was charged in U.S. federal court last year with five felonies - including providing professional athletes with performance-enhancing drugs and smuggling human growth hormone across the border - and he is still under investigation in Canada. He has not entered a plea yet in the U.S. case.

Galea has treated elite athletes such as Tiger Woods, Alex Rodriguez, Jose Reyes and Carlos Beltran and used PRP on Reyes and Woods. Both Reyes and Woods have denied that Galea gave them performance-enhancing drugs during their treatment.

The North America Platelet-Rich Plasma Symposium will also feature guest speaker/participant Dr. Joseph Purita, the Boca Raton orthopedist who performed a stem cell procedure on Yankees righthander Bartolo Colon last year. Purita advocates HGH use in his practice, although he has said he did not administer growth hormone to Colon. The Colon procedure was done in the pitcher's native Dominican, but it is not considered illegal in the U.S. Still, Major League Baseball is investigating Purita because of the HGH link.

Human growth hormone is banned by MLB, but major league players are not tested for it.

The symposium is scheduled to have live demonstrations of PRP therapy.

"It is hard to imagine any legitimate medical conference would take the risk of inviting someone to speak

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May 20, 2010

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March 11, 2010

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who is under indictment for illegally treating patients, unless they value the show and its publicity more than ethics and a patient's health," says Travis Tygart, the CEO of the United States Anti-Doping Agency, referring to Galea.

A Harvest spokeswoman said of the choice to include Galea and Purita, "(Harvest) has nothing but positive things to say about these doctors. They definitely put patients first."

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Pac-Man 30th anniversary: Google celebrates with free online Pac-Man game hidden in logo - go play!

Cher's daughter Chastity Bono is changing gender from female to male

Dr. Anthony Galea dropped as moderator of Toronto medical symposium, Dr. Lewis Maharam says

BY TERI THOMPSON AND CHRISTIAN RED
DAILY NEWS SPORTS WRITERS
Friday, June 17, 2011

Toronto physician Anthony Galea's moment in the bright lights was short-lived.

Galea, who was indicted in U.S. federal court last year on charges that include providing human growth hormone to professional athletes and smuggling HGH across the border, was to moderate a symposium on platelet-rich plasma therapy Sept. 9 in Toronto.

The inclusion of Galea in the North America Platelet-Rich Plasma Symposium created an uproar in the anti-doping field and the sports medicine community. The event's company sponsor, Harvest Technologies, was left to defend its choice of Galea and another controversial panelist, Dr. Joseph Purita.

But according to Dr. Lewis Maharam, the past president of the New York Chapter of the American College of Sports Medicine, a Harvest representative recently informed him that Galea - who has treated Tiger Woods and Jose Reyes with PRP - had been dropped. It's unclear what forced Harvest to cancel Galea's appearance.

"I'm happy someone made the decision to remove Galea," said Maharam.

In a June 5 Daily News article about the symposium, United States Anti-Doping Agency CEO Travis Tygart sounded off on the choice of Galea: "It is hard to imagine any legitimate medical conference would take the risk of inviting someone to speak who is under indictment for illegally treating patients, unless they value the show and its publicity more than ethics and a patient's health," Tygart said. Maharam said then that Galea's inclusion was "destroying the reputation of a treatment that is amazingly good."

A Harvest spokeswoman said last month that the company "has nothing but positive things to say about these doctors (Galea and Purita). They definitely put patients first."

Calls and emails to Harvest by The News were not returned. Galea's U.S. attorney Mark Mahoney did not return an email or text message.

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Cher's daughter Chastity Bono is changing gender from female to male

Dr. Lewis Maharam says Tiger Woods still has to answer questions about ties to steroid-tainted doc

BY TERI THOMPSON
DAILY NEWS SPORTS WRITER
Friday, February 19, 2010

Tiger Woods railed against charges he'd used performance-enhancing... (Skipper/Pool)

Dr. Lewis Maharam, chairman of the Board of Governors, International Marathon Medical Directors Association and the former medical director of the New York Road Runners and ING New York City Marathon, found this statement among the more interesting made by Tiger Woods in his televised remarks Friday: "Some people have made up things that never happened. They said I used performance-enhancing drugs. This is completely and utterly false."

Maharam wasn't sure who Woods was referring to when the golfer said he'd been accused of using PEDS, but his name did come up when one of his physicians, Dr. Tony Galea, became embroiled in an investigation after the sports doctor's assistant was busted with drugs at the U.S.-Canadian border and his Toronto office was raided by the Royal Canadian Mounted Police.

RELATED ARTICLES

Keith Kleven, who helped Tiger Woods turn from golf geek to...
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Buffalo FBI probing Tiger Woods' doctor Tony Galea for...
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Plasma

The assistant, Mary Anne Catalano, said she was carrying human growth hormone and a derivative of calves' blood, Actovegin, for her boss. Actevegan is not legal in the U.S. and not approved in Canada. Galea was hit with four drug chargers and is still under investigation.

Galea, who is not licensed to practice medicine in Florida, had treated Woods in Orlando with platelet-rich plasma therapy to help him recover from a knee injury. It also came to light that Woods had been treated by Las Vegas trainer Keith Kleven, who worked with Victor Conte and the BALCO crew a few years ago.

Dr. Maharam is certain of one thing: He's got some questions for Woods on the PED front.

"I was impressed with how well he rehearsed this apology and was struck by when he said, 'I'm so sorry', - there was a beautiful pause, he looked up at camera and continued, clearly rehearsed. But most of all, some of the things he said needed follow-up questions, especially the statement that he never used performance-enhancing drugs. Here are the questions I would have asked:

Why did you choose to work with a physician, not licensed in the U.S., who specializes in performance-enhancing drugs?

Who recommended him to you?

How often did you see him?

Would you be willing to have your blood saved and re-tested once there is a proper test available to detect human growth hormone?

How would you react if your blood test showed up positive. What would that mean?

You apologized to kids who look up to you, saying actions speak louder than words. Would you tell kids not to use human growth hormone or steroids?

EXHIBIT E

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230 Browns Line
Toronto, Ont
M8W 3T4

Phone 416 620 6861
Fax 416-620-9774
E-mail anthonygalea@mac.com

Dr. Anthony Michael Galea

Education

McMaster University Medical School, Hamilton, Ontario Canada

M.D. obtained 1986

University of Waterloo, Waterloo, Ontario
Honours B.Sc
Major: Health Studies

Obtained in 1983

Canadian Academy of Sports Medicine,
Ottawa, Canada

Diploma in Sports Medicine 1989

American Academy of Sports Medicine Physicians,
California, U.S.A

Certified with special competency in the area of
Sports Medicine 1988

Canadian Center for Drug Free Sport,
Ottawa, Canada

Certified Doping Control Officer

Work Experience

Director

1990—Present—Consultant to numerous International Athletes both Amateur and Professional, Including NFL, NHL, and MLB players

2002—Present Director, ISM Health & Wellness Center, Toronto Ontario, Working with Plasma Rich Platelet therapy for the treatment of Sports related injuries

1999--2001 LifeMark Health Inc. - National Director of Sports Medicine – Canada

1999—2000 The Fitness Institutes - Director of Medical Services

1988 –1999 Director, The Institute of Sports Medicine & Human, Performance, 110-185 The West Mall, Etobicoke, Ontario

Team Physician

2005, 2009 Chief Medical Officer Team Canada Maccabi Games, Israel

2008-2009 Head Physician International Bowl, Toronto Ontario

2004-2009 Toronto Argonauts Professional Football Team—2004 Grey Cup Champions

2007 Iron Man Compitition Kona, Hawaii

2004 St. Vincent Grenadine World Cup Soccer Team

2000 Summer Olympic Games, Sydney, Australia 100m Sprinters – Donivan Bailey , Bruni Surin, Obdale Thompson

2000 World Freestyle Ski Championships, Blackcombe, Canada (Team Doctor Denmark)

1999 World Track & Field Championships, Seville, Spain

1998 Olympic Winter Games, Team Canada, Nagano, Japan

Canadian Freestyle Ski Team:

1997- World Championship, Nagano, Japan

1997- World Cup Event, Lake Placid, U.S.A

1997- World Cup Event, Meringen, Switzerland

1997- World Cup Event, Blackcombe, Canada

1996- World Cup Event, Lake Placid, U.S.A

1996- World Cup Event, Blackcombe, Canada

1995- World Cup Event, Lake Placid, U.S.A

1995- World Championships Freestyle Skiing, La Clusaz, France

1994- Canadian Nationals, Quebec, Canada

1994- Meringan, Switzerland

1994- Blackcombe, Canada

1993- Mt. Gabriel, Quebec, Canada

1993- Lake Placid, U.S.A.

1993- Blackcombe. Canada

1992- Altenmark, Austria

1992- Lake Placid, U.S.A.

1991- Mt. Gabriel, Quebec, Canada

1991- Lake Placid, U.S.A.

1990- La Clusaz, France

1989- Tignes, France

1989- La Plagne, France

1989- Suomotunturi, France

Sports Medicine Physician

Tennis Canada

1990- World Sky Dome Tennis Championships

1991, 1992, 1993, &1994- Players International Tennis Championships, Toronto, Canada

1995, 1997- DeMaurier Women's WTA Canadian Open Tennis Championships

1996- DeMauier Mens ATP Canadian Open Tennis Championships

Athletics

The Toronto Marathon, Toronto, Canada

1990, 1991, 1992, 1993, 1994, & 1995 Toronto Marathons: responsible for the care & supervision of competing participants

Figure Skating

1993- The Canadian National Figure Skating Championships, Hamilton One of the roster of physicians responsible for the event coverage

Co-ordinating Physician

The Coor's Light Summer Running Series 1990, 1991, 1992, 1993 Ontario, Canada

Doping Control Officer

Canadian Center for Drug Free Sport, Ottawa, Canada

1990, 1991, 1992- Chief Doping Control officer for the Hamilton Spectator Games, Hamilton, Canada

1990- Doping Control Officer for the Canada Cup Cross Country Ski Championships

1991, 1992, 1993- Doping Control Officer for the Sun Life National Tennis Championships, Mississauga, Canada

1990, 1991, 1992, 1993- Conducted no notice drug tests on behalf of Canadian Center for Drug Free Sport, Allenstown, Pennsylvania, U.S.A. & to the National Training Camps for Canoeing & Track &

Field in Florida, U.S.A.

1992, 1993- Conducted testing on Cuban athletes on behalf of the I.A.A.F. Havana, Cuba

1996- Conducted a seminar on banned substances & methods at the Paralympics, Atlanta, Georgia

Faculty Teaching Position

Department of Family Medicine, University of Toronto

Lecture on various topics in sports medicine to family practice residents

Supervise rotating residents at our sports medicine facility

Chairman

Selection Committee, Etobicoke Sports Hall of Fame

Sports Science Committee, Canadian Freestyle Ski Team

Chairman, Selection Committee

University of Toronto, Sports Medicine Fellowship Program

Founding Member

World Freestyle Sports Science Committee

Canadian Medical Team

1998 Olympic Winter Games, Nagano, Japan

Founding Member Vice-Chairman

1993-2001 Board of Governors, City of Etobicoke Sports Hall of Fame

PROFESSIONAL SOCIETIES:

Canadian Academy of Sports Medicine

American College of Sports Medicine

Canadian Medical Association

Ontario Medical Association

World Society for Tennis Medicine

Member of the National Association of Disability Evaluating Professionals

LECTURES & PUBLICATIONS

2007-2008 Lecturer Pfizer Canada, Sports Medicine Series

2007 Book publication—Dr Galea's Secrets to Optimal Health

July 2005 Guest Speaker, International Sports Symposium, Israel

May 2005 , Primary Care today : Education conference & Medical exposition; Lecture " Common Sport Medicine Injuries In Family

Practice”

Chairman for the Freestyle Ski Team Sports Medicine Symposium held in Whistler B.C. Jan 1994, Jan 1995, & Jan1996

Lecturer to the Insurance Rehabilitation Liaison Committee Day Nov 1993

Lecturer University of Toronto Residents Clinical Day 1990 & 1992

Lectured St. Joseph’s Health Center & Doctors Hospitals Clinical Days 1990

Lectured to the Toronto Task Force on Drug Abuse

Lectured to various national teams on behalf of the Canadian Center for Drug Free Sport

Patellofemoral Syndrome- Beyond Empirical Diagnosis Physician & Sports Medicine Journal: 48-58; April 1994

Key Note Speaker- the addiction research Foundation’s Workshop on **STEROIDS … BODY IMAGE OR BODY DAMGE?** May 11/94

1994 TSN Television Documentary on Steroids

1995 Canadian Chiropody Association lecture on Patellofemoral Syndrome

1996 Telemedicine Orthopedic Rounds “Non-operative Management of Foot and Ankle Injuries-A Sports Medicine Approach